

TEST REPORT

Dermatologically controlled home in use test

Test product: DermaNova Active Skin Care Cream A
DermaNova Active Skin Care Cream B

Test report: Pharma Medico
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Contents

1	Introduction	3
1.1	General Data	3
2	Details of the experiment	4
2.1	Selection of volunteers	4
2.2	Performance of the study	4
2.3	Documentation	5
3	Results and Discussion	6
3.1	Characterization of the volunteers	6
3.2	Compatibility parameters	7
3.3	Effectiveness parameters	8
3.4	Cosmetic parameters	10
4	Summary	11
5	Literature	12

1. Introduction

1.1 GENERAL DATA

Aim of the study:	To assess the skin tolerance, effectiveness and cosmetic acceptance of the products DermaNova Active Skin Care Cream A for Psoriasis and DermaNova Active Skin Care Cream B for Psoriasis during a three weeks dermatologically controlled application test.
Products tested:	DermaNova Active Skin Care Cream A for Psoriasis. DermaNova Active Skin Care Cream B for Psoriasis.
Test persons:	20.
Sex:	10 female, 10 male.
Age:	27-72 years.
Region tested:	Affected parts of the body.
Frequency application:	At least once a day.

2. Details of the experiment

2.1 SELECTION OF VOLUNTEERS

A group of ten female and ten male volunteers at the age of 27 to 72 years takes part in the study.

At the beginning of the study, the dermatologist in charge draws up an anamnesis of each volunteer. The results of this skin history act as a basis for the decision of the suitability of the volunteers for this study. During the anamnesis the volunteers are asked if they have any allergies and diseases. All of the volunteers taking part in this study are characterised as psoriasis sufferer. One volunteer has an allergic rhinitis, and another volunteer has a contact allergy and a drug allergy.

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.

2.2 PERFORMANCE OF THE STUDY

Each volunteer is assigned to use one test product for psoriasis on the affected parts on each site of the body. At least once a day the creams A and B are applied on the affected parts of the body site and spread in an evenly layer. The body sites of the volunteers are treated randomised with test product A or B.

The volunteers are allowed to continue to use their normal cleansing products, bath soap, shower gels etc., but they are not allowed to change these products or to add new ones during the test. No skin care products other than the test products are permitted to be applied on the treated parts of the body. Decorative cosmetics can be applied as usual.

2.3 DOCUMENTATION

Before the start of the study the different skin types of the volunteers are documented by the test manager. Additionally the test persons judge subjectively their skin sensitivity in the face and at the body as well as the percentage part of their body skin, which is affected by the psoriasis.

The volunteers indicate which skin care products they normally use and if they have taken any medication.

In order to test the effectiveness of the test products, the volunteers document a possible change of the suppleness and of the smoothness of the skin. Furthermore the influence of the test products on the dryness, the elasticity, the firmness and the appearance is judged. In case of a change of the mentioned parameters, the degree of the change is classified with a scale from 1 (minimum) to 5 (extremely better or worse).

In addition, the effectiveness of the test products for itching and for psoriasis is examined. The volunteers judge subjectively whether the itching and the psoriasis has stopped, got eased or increased.

For the evaluation of the unwanted effects caused by the test products eye reddening, eye itching, tears, skin reddening, dryness, flaking, itching, stinging, tension and the formation of papules are documented. The characterization of the unwanted effects is made with a scale from 1 (minimum) to 5 (very strong). Additionally the duration (briefly, 5 minutes, 15 minutes, 30 minutes, 1 hour, longer than one hour and constantly) of the felt negative reactions is indicated.

At the end of the three weeks the volunteers fill out a questionnaire and give their rating on appearance, consistency, spreadability, absorption and stickiness on the skin. Moreover the fragrance and the fragrance intensity of the test products in the container and on the skin are documented.

Means and standard deviations are calculated from the numerically coded data reported on the questionnaire. Frequencies and percentages are given, too.

3. Results and discussion

3.1 CHARACTERIZATION OF THE VOLUNTEERS

After three weeks of application the 20 volunteers complete a questionnaire to rate the test products for psoriasis. No volunteer quits the study for incompatibility problems.

The following table presents an overview of the different skin types as rated by the test manager.

SKIN TYPE	QUANTITY [%]	
	FACE	BODY
Mixed skin	50	15
Normal skin	15	35
Dry skin	20	50
Oily skin	15	-

Table 1: Relative frequencies of the different skin types

SKIN SENSITIVITY	QUANTITY [%]	
	FACE	BODY
Normal	55	85
Sensitive	30	10
Very	15	5

Table 2: Relative frequency of the skin sensitivity

55% respectively 85% of the volunteers describe their skin sensitivity as normal on the face, respectively on the body. 30% respectively 10% rate their skin as sensitive on the face respectively on the body. In addition, 15% respectively 5% rate their skin as very sensitive on the face respectively on the body.

Twelve of the 20 volunteers regularly use skin care products.

From 5% to 60% of the skin of the volunteers is affected by psoriasis. The average affected skin area is 26%.

3.2 COMPATIBILITY PARAMETERS

None of the volunteers discontinues the study due to tolerance problems. A final rating of all volunteers is included in the evaluation.

The following table gives a summary of the occurred incompatibilities.

PARAMETER	DERMANOVA CREAM A FOR PSORIASIS			DERMANOVA CREAM B FOR PSORIASIS		
	Score	% of the volunteers	Reaction points	Score	% of the volunteers	Reaction points
Eye reddening	0.0	0.0	0	0.0	0.0	0
Eye itching	0.0	0.0	0	0.0	0.0	0
Eye watering	0.0	0.0	0	0.0	0.0	0
Skin reddening	3.0	5.0	3	3.0	5.0	3
Dryness	3.0	5.0	3	3.0	5.0	3
Flaking	0.0	0.0	0	0.0	0.0	0
Itching	3.0	5.0	3	3.0	5.0	3
Stinging	0.0	0.0	0	0.0	0.0	0
Skin tension	0.0	0.0	0	0.0	0.0	0
Formation of papules	0.0	0.0	0	0.0	0.0	0

Table 3: Proportional frequencies of unwanted effects and reaction points caused by the test products. Grading scale: 1 = minimal to 5 = very strong

The regular application of the test products caused the same two volunteers (no. 4 and 12) unwanted effects with an average shaping. Skin reddening, dryness and itching are documented for these volunteers. For volunteer no. 4 a clear reaction for skin reddening is documented after the use of both test products. Volunteer no. 12 documents a clear dryness and itching after the use of both test products. Because only two volunteers show incompatibilities with an average score both test products for psoriasis achieve a good to very good skin compatibility in this study. Therefore both test products obtain an average compatibility score of 1.7.

The overall rating of the compatibility gets a mean score of 2, which is very good for both test products. In conclusion, a differentiation between the two test products cannot be done by the results of this study regarding the tolerance.

3.3 EFFECTIVENESS PARAMETERS

The following table shows the volunteers rating of the effectiveness of the test products for psoriasis.

PARAMETER	RATING	Directly after product application		8 hours after product application	
		A	B	A	B
Suppleness	better	85.0	85.0	35.0	25.0
	worse	0.0	0.0	0.0	0.0
	same	15.0	15.0	65.0	75.0
Smoothness	better	90.0	90.0	35.0	25.0
	worse	0.0	0.0	0.0	0.0
	same	10.0	10.0	65.0	75.0
Dryness	better	85.0	85.0	50.0	40.0
	worse	5.0	5.0	5.0	5.0
	same	10.0	10.0	45.0	55.0
Elasticity	better	50.0	50.0	35.0	25.0
	worse	0.0	0.0	0.0	0.0
	same	50.0	50.0	65.0	75.0
Firmness	better	35.0	30.0	25.0	25.0
	worse	0.0	0.0	0.0	0.0
	same	65.0	70.0	75.0	75.0
Appearance	better	70.0	70.0	50.0	45.0
	worse	5.0	5.0	5.0	5.0
	same	25.0	25.0	45.0	50.0

Table 4: Percentages for the test products A and B for psoriasis in the effectiveness parameters

As shown in table 4 the effectiveness parameters is judged mostly positive. Directly after the application of the test products 85% to 90% of the volunteers report that the parameters suppleness, smoothness and dryness of the skin improve directly after the use of both test products. 50% of the volunteers report that the elasticity increases directly after the application of both test products. 35%, respectively 30% of the volunteers document that the firmness of the skin increases directly after the application of product A, respectively product B. All in all 70% of the volunteers think that the appearance of the skin improves immediately after the application of both test products. Eight hours after the application these positive changes partly vanish. Now 35% respectively 25% of the volunteers still report that the suppleness and smoothness are improved after the use of product A, respectively product B. 50% respectively 40% can still feel a better change in the dryness of their skin after the use of product A respectively product B. Similar ratings are given for the rest of the effectiveness parameters. After eight hours of application the volunteers prefer slightly the test product A in these parameters.

PARAMETER	RATING	Number of volunteers		Average duration in hour	
		A	B	A	B
Effect on psoriasis	strong improvement	35	25	19,6	19,6
	improvement	40	50	14,0	16,8
	no effect	25	25	-	-
	worse	0	0	-	-
Effect on itching	has stopped	50	40	16,8	19,1
	eases	25	30	6,1	6,3
	no effect	25	30	-	-
	increases	0	0	-	-

Table 5: Ratings of the test products in the effectiveness for Psoriasis

A positive effect on the psoriasis is reported by 75% of the volunteers after the use of test product A. 35% of the volunteers describe a strong improvement on their skin and 40% an improvement. For the test product B also 75% of the volunteers document a bettering of their psoriasis problems. In this case 25% can feel a strong improvement and 50% can feel an improvement.

As shown in table 5, 50% respectively 40% of the volunteers document that the itching of their skin has stopped after the use of the test product Dermanova Active Skin Care Cream A, respectively Cream B. Additionally further 25% respectively 30% of the volunteers report that the itching eases after the application of the test product A respectively test product B. Only 25% do not feel an effect after the use of product A and 30% realize no effect on the itching after the application of product B. In conclusion, 75% of the volunteers document a positive effect for itching in this study after the use of test product A. In comparison 70% of the volunteers report changes to a better for product B. It can be concluded from the comments of the volunteers that they are pleased by the alleviation of the itching caused by both test products. All positive effects described by the volunteers last several hours. In spite of the fact that less volunteers documented a stopping of the itching; they report a longer effect for the test product B. Therefore a differentiation of the two test products in regard to their effect for psoriasis and itching cannot be made. It seems to be that already the enriched basic formulations ease the effect of the disease.

3.4 COSMETIC PARAMETERS

The following table gives a summary of the average ratings for the cosmetic parameters.

PARAMETER	NUMBER OF VOLUNTEERS IN %					
	DERMANOVA CREAM A			DERMANOVA CREAM B		
Consistency	too thick	too thin	just right	too tick	too thin	just right
	15	0	85	20	0	80
Fragrance intensity	too strong	too low	just right	too strong	too low	just right
- in the container	70	0	30	65	0	35
- on the skin	65	0	35	60	0	40

	AVERAGE SCORE	
	DERMANOVA CREAM A	DERMANOVA CREAM B
Spread ability	1.83	1.85
Absorption	1.95	2.00
Stickiness	1.45	1.45
Fragrance in the container	3.18	3.05
Fragrance on the skin	3.05	2.88
Appearance	2.63	2.63
Care effect	1.78	1.90

Table 6: Average ratings for the cosmetic parameters for both test products after three weeks of application (1 = very good; 5 = very bad) (n = 20)

For the cosmetic parameters spreadability, absorption, stickiness and care effect both test products obtain good to very good scores in the subjective rating of the volunteers. The named parameters get scores from 1.45 to 2.00. That means that the volunteers are satisfied to very satisfied with these parameters. 85% respectively 80% of the volunteers think that the consistency of test product A respectively B is "just right". These ratings are reflected in the average scores for the parameters appearance. The scores for the parameters stickiness show that the volunteers do not notice a sticky feeling on their skin after the application of both test products. All in all, the volunteers are satisfied with the cosmetic parameters. Also the cosmetic parameters do not allow to make a clear differentiation between the two test products.

4. Summary

Most of the application properties of both test products for psoriasis are rated with scores from 1.45 to 2.00 for the parameters spreadability, absorption, stickiness and care effect. Accordingly these parameters are classified as good to very good. The majority of volunteers rate the consistency of both products as "just right" (A: 85%; B: 80%). There are minimal advantages in favour of Cream A for all parameters.

Only two volunteers report unwanted effects. One volunteer documented a skin red-dening. The other one reports dryness and itching after the use of both test products. The overall compatibility is rated good to very good for Cream A and Cream B. Therefore both test products for psoriasis achieve a good skin compatibility in this investigation. Nevertheless irritations cannot be excluded in few individual cases.

A total of 75% of the volunteers see an improvement of psoriasis after the use of the test product. 35% describe a strong improvement after the use of Cream A and 25% for the test product B.

75%, respectively 70% of the volunteers document a positive effect for the itching, whereby 50% document a total ease of the itching after the use of test product A and 40% for product B. Many volunteers describe that the itching stops for several hours after the use of both products. 55% respectively 60% of the volunteers are so satisfied with the test product A respectively B, that they would buy it. It can be taken from the comments of the volunteers, that they especially like the alleviation of itching and the healing of their psoriasis. A clear differentiation between the two products cannot be made by the result of this study.

5. Literature

- 1 The World Medical Association, World Medical Association Declaration of Helsinki, Fernay, Voltaire, France (1989)