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LAMBERG Unicare SA
Alleestrasse 5

CH-3703 Aeschi bei Spiez

date: Münster, 25.09.2000

Specialist, dermatological report about a

4-week clinical dermatological

APPLICATION TEST

with a conclusive

EPICUTANEOUS TEST

in accordance with international guidelines

Description of the product:

Lactena Intimate Wash Lotion

Client: LAMBERG Unicare SA
Alleestrasse 5
CH-3703 Aeschi bei Spiez

Test persons: 40 female and 10 male test persons with skin conditions in the genital and anal region

Test duration: 4 weeks

Concentration used in epicutaneous test: product 1%, 2% and 5% diluted in distilled water

CONCEPT AND METHOD

The aim of this examination was to analyse precisely the named product on its compatibility in accordance with dermatological clinical criteria. The subjects were able to consult the dermatologist involved in the examination on a daily basis about objective and subjective changes to the mucous membrane.

Before beginning the application test, all subjects were dermatologically examined. In addition, all of the test persons were obligated to refrain from using other intimate hygiene products during the test period.

Only participants who found pathological changes to the skin in the genital and anal region were accepted into the test group. Inclusion criteria were tinea cruris, tinea genitalis, anal tinea, haemorrhoids, pruritus, genitalis and microbial eczema in the genital and anal region. Applying the product should also range over the time of menstruation.

Medical therapy for the underlying cause followed in addition to applying the product.

Each test person applied the product once to twice a day where possible to care for the skin in the genital and anal region. Where necessary, clinical checks about the state of the skin could be carried out by the dermatologist involved in the testing. Upon completion of the test, the subjects received questionnaires to subjectively evaluate the product.

Final epicutaneous tests after the end of the 4-week application time should verify the risk of allergies to the product.

The epicutaneous test is model evidence of a primary irritant or a contact allergy (by provoking allergic reactions on the skin on subjects already sensitised) through contact with the product to be investigated which is epicutaneous, localised and for a limited period of time.

In order to facilitate the absorption of the samples, they are brought under occlusive conditions during the epicutaneous testing. In order to elicit a positive reaction, the sensitivity threshold must be exceeded.

The product to be examined is 1%, 2% and 5% diluted in distilled water and applied and fixed to the clinically healthy skin on the inside of the forearm by using a standard test plaster (Leukotest (R), Fa. Hartmann).

The test plasters are removed after an exposure period of 24 hours and the test areas are evaluated firstly by a specialist for dermatology and allergology. A second and third evaluation are carried out after 48 and 72 hours.

If the epicutaneous test is performed after a 4-week application time, it gives information about not only irritant reactions but also about the sensitivity potential of the applied product.

PROBLEM

Over 30 year ago, the armpits and the inframammary regions belonged to the intimate parts of the body; today, only the inguinal, genital and anal regions are understood under this term. Meanwhile, the anogenital region has also become included in daily skin care. In this region, it is known for producing increased body odours due to bacterial activity. Normal washing active substances (soaps and syndets) quickly show side affects if used frequently due to increased dehydration and irritant reactions. That said, it has been frequently shown in specialist literature up to now that locally adapted skin cleansing of the anogenital region is of a very delicate nature, like the other joints of the body (throat, armpit, crook of the arm). In women to a particularly large extent, mucocutaneous junctions are present. In addition, areas of skin lie next to each other. Apocrine scent glands and sweat glands, as well as the mucous glands in the mucous membranes, are present in large numbers. Ultimately, in this area of the body, excrement is voided which leads to an additional strain on the skin. Factors which increase skin irritation are: 1. lipases and proteases from the stool and, as a result, the establishment of bacteria, 2. by alkalisng the skin pH (urine), the irritation caused by stools is increased by a factor of 5, 3. faecal enzymes are activated by contact with urine, 4. occlusion alkalisng the skin, 5. hyperhydration and friction strain the skin barriers, 6. urease (partly bacterial) metabolises urea to ammonia.

With eczema in the anogenital region, treating the skin must be carried out with strong anti-inflammatory medication. Subsequently, the skin in this area must be consistently cared for in order to stabilise the healing skin. With this skin care, from a dermatological point of view it depends not just on the lipid content but also on the intake of moisture. The creams used must offer a well-balanced ratio of fat and moisture contributions to care for dry and irritated skin in the anogenital area if the treatment is to be successful in the long term. According to dermatological experience from the last 20 years, the fact that mild detergents especially intended for sensitive skin should be used within such a process goes without saying.

Habits for cleansing the skin have significantly changed in the last few years; showering regularly or bathing using so-called syndets and washing the hair almost daily are considered essential for body hygiene (Braun-Falco, 1981). However, repeated washing intervenes with the ecosystem of the skin to a greater or lesser extent. The type and extent of the changes with regard to sebum, stratum disjunctum corneum and skin flora depend not only on the skin type but also the type and composition of the detergent used (Hartmann et al., Voss und Cronemeyer, 1983). From a dermatological point of view, cleansing the skin of healthy people in general and those with skin conditions in particular still remains a real *crux medicorum* (Giss, 1982).

Therefore one of the primary aims of the study was to investigate precisely the effect of the product on extremely sensitive skin of patients with skin conditions.

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SUBJECTS

Sub. no.	Condition	Name	m/f	Age
1	Tinea cruris	G.L.	f	34
2	Anal tinea	H.M.	f	48
3	Haemorrhoids	G.St.	f	24
4	Tinea genitalis	M.B.	f	34
5	Haemorrhoids	A.W.	f	56
6	Tinea genitalis	M.E.	f	45
7	Haemorrhoids	S.G.	f	52
8	Anogenital pruritus	M.Fe.	f	42
9	Tinea genitalis	B.No.	f	34
10	Haemorrhoids, Tinea genitalis	H.B.	f	49
11	Tinea anogenitalis	E.K.	f	43
12	Haemorrhoids	G.H.	f	68
13	Tinea genitalis	Sy.B.	f	32
14	Anogenital pruritus	H.Be.	f	51
15	Tinea anogenitalis	S.L.	f	45
16	Tinea anogenitalis, Haemorrhoids	D.H.	f	62
17	Tinea genitalis	St.P.	f	54
18	Tinea anogenitalis	A.H.	f	34
19	Anogenital pruritus	H.W.	f	68
20	Tinea anogenitalis	N.Ba.	f	24
21	Haemorrhoids	B.Gr.	f	58
22	Tinea anogenitalis	S.B.	f	24
23	Tinea inguinalis	B.R.	f	34
24	Anogenital pruritus	E.H.	f	72
25	Tinea anogenitalis	T. Schn.	f	78
26	Tinea genitalis	S.H.	f	38
27	Haemorrhoids	E.St.	f	62
28	Tinea anogenitalis	G.H.	f	36
29	Anogenital pruritus	M.B.	f	69
30	Tinea anogenitalis	Th.R.	f	52
31	Haemorrhoids	A.T.	f	70
32	Tinea anogenitalis	W.G.	f	46
33	Anogenital pruritus	B.E.	f	42
34	Tinea cruris	D.H.	f	44
35	Haemorrhoids	K.Ri.	f	49
36	Tinea anogenitalis	J.Si.	f	51
37	Tinea anogenitalis	A.S.	f	54
38	Anal tinea	B.U.	f	58
39	Tinea anogenitalis	M.Str.	f	62
40	Anogenital pruritus	A.Ku.	f	39

SUBJECTS

Sub. no.	Condition	Name	m/f	Age
1	Tinea anogenitalis	B.S.	m	41
2	Tinea anogenitalis	St.Br.	m	47
3	Haemorrhoids	T.G.	m	56
4	Tinea anogenitalis, Haemorrhoids	H.G.	m	72
5	Tinea anogenitalis Haemorrhoids	W.St.	m	64
6	Tinea anogenitalis	H.Kr.	m	74
7	Tinea anogenitalis, Haemorrhoids	M.K.	m	41
8	Anogenital pruritus, Haemorrhoids	U.No.	m	61
9	Tinea genitalis, Haemorrhoids	H.Sch.	m	72
10	Tinea anogenitalis	G.H.	m	68

Explanation:

Tinea anogenitalis = fungal infection in the anal and genital region

Tinea genitalis = fungal infection in genital region

Tinea cruris = fungal infection in the groin

Anal tinea = fungal infection in the anal region

Anogenital pruritus = itching in the anal and genital region

Haemorrhoids = swelling similar to "varicose veins" in the veins of the anal region

DERMATOLOGICAL EXAMINATION

1. Before beginning the application test

None of the test persons exhibit healthy skin in the anogenital area. The respective dermatological diagnoses are stated in the tables.

2. During the application test

None of the 50 test persons showed pathological skin changes in the anogenital region over the course of the 4-week application test which resulted from using the product. Therefore, interruptions to testing or even specialist skin treatments were not necessary in any case.

3. After the end of the application test

At the concluding dermatological examination after the test ended, there were no pathological skin changes in the anogenital region in any of the 50 test persons.

DERMATOLOGICAL ASSESSMENT CRITERIA

1. Dryness (xerosis) with flaking of the skin
2. Possible eczema reaction
3. Feeling of tightness after applying the product
4. Formation of rhagades (formation of cracks) in the area of application
5. Dry desquamation in the area of applying the product
6. Possible increased itching after applying the product

SUBJECTIVE ASSESSMENT CRITERIA

1. Feeling of tightness after applying the product
7. Possible itching after applying the product
2. Subjective skin sensation after applying the product
3. Scent of the product
4. Reduced itching after using the product

Questionnaire about Lactena Intimate Wash Lotion after completing a 4-week application period

1. How long did you have the itching for when the study began?

- Days
Weeks
Months
Years

2. Have you suffered from this kind of condition before?

- no
 yes How often?: _____ In which intervals?: _____

3. Have you received prescribed medication in addition to the intimate wash lotion?

- no
 yes, which?: _____ For how long? _____

4. Have you used other wash products (sitz baths) or topical products (creams, ointments etc.) in addition to the intimate wash lotion?

- no
 yes, which?: _____

5. Rate the itching before treatment on a scale of 1 - 6 (1=no itching, 6=severe itching)! (please tick)

- 1 2 3 4 5 6

6. Rate the itching after treatment on a scale of 1 - 6 (1=no itching, 6=severe itching)! (please tick)

- 1 2 3 4 5 6

7. How did you find the anti-itching effect of the intimate wash lotion after the first application? (1=very good, 6=very bad) (please tick)

- 2 3 4 5 6

8. How did you find the anti-itching effect of the intimate wash lotion overall? (1=very good, 6=very bad) (please tick)

9. Effect of the intimate wash lotion in general? (1=very good, 6=very bad) (please tick)

- 1 2 3 4 5 6

10. How did you find the product during menstruation? (1=very good, 6=very bad) (please tick)

- 1 2 3 4 5 6

11. Finally, please state how you would evaluate the product overall.
Very good () good () satisfactory () poor () very poor ()

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Evaluation of the questionnaire which was handed out to the subjects at the concluding dermatological examination to evaluate the product stated above and was prepared with the patient:

1. How long did you have the itching for when the study began?

Days **4 days: 4x** **8 days: 6x**
 Weeks **2 weeks: 24x** **4 weeks: 12x**
 Months **1 month: 4x**
 Years

2. Have you suffered from this kind of condition before?

no **38x** **yes: 12x, intervals: 3 months to 6 years**
 yes How often?: In which intervals?

3. Have you received prescribed medication in addition to the intimate wash lotion?

no **8x no medication 34x antifungal medication, 8x combined product of antifungal and anti-inflammatory medication**
Application time 3-4.5 weeks

yes: name: For how long?

4. Have you used other wash products (sitz baths) or topical products (creams, ointments etc.) in addition to the intimate wash lotion?

no **50x no**
 yes, which?:

5. Rate the itching before treatment on a scale of 1 - 6 (1=no itching, 6=severe itching)! (please tick)

1	2	3	4	5	6
	6x	12x	14x	18x	

6. Rate the itching after treatment on a scale of 1 - 6 (1=no itching, 6=severe itching)! (please tick)

1	2	3	4	5	6
46x	4x				

7. How did you find the anti-itching effect of the intimate wash lotion after the first application? (1=very good, 6=very bad) (please tick)

1	2	3	4	5	6
28x	12x	5x	5x		

8. How did you find the anti-itching effect of the intimate wash lotion overall? (1=very good, 6=very bad) (please tick)

1	2	3	4	5	6
36x	12x	2x			

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9. How did you find the nurturing effect of the intimate wash lotion overall? (1=very good, 6=very bad) (please tick)

1 2 3 4 5 6
14x 22x 8x 6x

10. How did you find the product during menstruation? (1=very good, 6=very bad) (please tick)

1 2 3 4 5 6
4x 12x (only 16 answers)

11. Finally, please state how you would evaluate the product overall.

very good	42
good	8
satisfactory	0
poor	0
very poor	0

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RESULTS FROM EPICUTAENOUS TEST

After the end of the 4-week application test

Test concentration: product 1 % diluted with distilled water.

Product: Lactena Intimate Wash Lotion

24 h	48 h	72 h	No.	Condition	Name	m/f	Age
-	-	-	1	Tinea cruris	G.L.	f	34
-	-	-	2	Anal tinea	H.M.	f	48
-	-	-	3	Haemorrhoids	G.St.	f	24
-	-	-	4	Tinea genitalis	M.B.	f	34
-	-	-	5	Haemorrhoids	A.W.	f	56
-	-	-	6	Tinea genitalis	M.E.	f	45
-	-	-	7	Haemorrhoids	S.G.	f	52
-	-	-	8	Anogenital pruritus	M.Fe.	f	42
-	-	-	9	Tinea genitalis	B.No.	f	34
-	-	-	10	Haemorrhoids, Tinea genitalis	H.B.	f	49
-	-	-	11	Tinea anogenitalis	E.K.	f	43
-	-	-	12	Haemorrhoids	G.H.	f	68
-	-	-	13	Tinea genitalis	Sy.B.	f	32
-	-	-	14	Anogenital pruritus	H.Be.	f	51
-	-	-	15	Tinea anogenitalis	S.L.	f	45
-	-	-	16	Tinea anogenitalis, Haemorrhoids	D.H.	f	62
-	-	-	17	Tinea genitalis	St.P.	f	54
-	-	-	18	Tinea anogenitalis	A.H.	f	34
-	-	-	19	Anogenital pruritus	H.W.	f	68
-	-	-	20	Tinea anogenitalis	N.Ba.	f	24
-	-	-	21	Haemorrhoids	B.Gr.	f	58
-	-	-	22	Tinea anogenitalis	S.B.	f	24
-	-	-	23	Tinea inguinalis	B.R.	f	34
-	-	-	24	Anogenital pruritus	E.H.	f	72
-	-	-	25	Tinea anogenitalis	T.Schn.	f	78
-	-	-	26	Tinea genitalis	S.H.	f	38
-	-	-	27	Haemorrhoids	E.St.	f	62
-	-	-	28	Tinea anogenitalis	G.H.	f	36
-	-	-	29	Anogenital pruritus	M.B.	f	69
-	-	-	30	Tinea anogenitalis	Th.R.	f	52
-	-	-	31	Haemorrhoids	A.T.	f	70
-	-	-	32	Tinea anogenitalis	W.G.	f	46
-	-	-	33	Anogenital pruritus	B.E.	f	42
-	-	-	34	Tinea cruris	D.H.	f	44
-	-	-	35	Haemorrhoids	K.Ri.	f	49
-	-	-	36	Tinea anogenitalis	J.Si.	f	51
-	-	-	37	Tinea anogenitalis	A.S.	f	54
-	-	-	38	Anal tinea	B.U.	f	58
-	-	-	39	Tinea anogenitalis	M.Str.	f	62
-	-	-	40	Anogenital pruritus	A.Ku.	f	39

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RESULTS FROM EPICUTAENOUS TEST

After the end of the 4-week application test

Test concentration: product 2 % diluted with distilled water.

Product: Lactena Intimate Wash Lotion

24 h	48 h	72 h	No.	Condition	Name	m/f	Age
-	-	-	1	Tinea cruris	G.L.	f	34
-	-	-	2	Anal tinea	H.M.	f	48
-	-	-	3	Haemorrhoids	G.St.	f	24
-	-	-	4	Tinea genitalis	M.B.	f	34
-	-	-	5	Haemorrhoids	A.W.	f	56
-	-	-	6	Tinea genitalis	M.E.	f	45
-	-	-	7	Haemorrhoids	S.G.	f	52
-	-	-	8	Anogenital pruritus	M.Fe.	f	42
-	-	-	9	Tinea genitalis	B.No.	f	34
-	-	-	10	Haemorrhoids, Tinea genitalis	H.B.	f	49
-	-	-	11	Tinea anogenitalis	E.K.	f	43
-	-	-	12	Haemorrhoids	G.H.	f	68
-	-	-	13	Tinea genitalis	Sy.B.	f	32
-	-	-	14	Anogenital pruritus	H.Be.	f	51
-	-	-	15	Tinea anogenitalis	S.L.	f	45
-	-	-	16	Tinea anogenitalis, Haemorrhoids	D.H.	f	62
-	-	-	17	Tinea genitalis	St.P.	f	54
-	-	-	18	Tinea anogenitalis	A.H.	f	34
-	-	-	19	Anogenital pruritus	H.W.	f	68
-	-	-	20	Tinea anogenitalis	N.Ba.	f	24
-	-	-	21	Haemorrhoids	B.Gr.	f	58
-	-	-	22	Tinea anogenitalis	S.B.	f	24
-	-	-	23	Tinea inguinalis	B.R.	f	34
-	-	-	24	Anogenital pruritus	E.H.	f	72
-	-	-	25	Tinea anogenitalis	T.Schn.	f	78
-	-	-	26	Tinea genitalis	S.H.	f	38
-	-	-	27	Haemorrhoids	E.St.	f	62
-	-	-	28	Tinea anogenitalis	G.H.	f	36
-	-	-	29	Anogenital pruritus	M.B.	f	69
-	-	-	30	Tinea anogenitalis	Th.R.	f	52
-	-	-	31	Haemorrhoids	A.T.	f	70
-	-	-	32	Tinea anogenitalis	W.G.	f	46
-	-	-	33	Anogenital pruritus	B.E.	f	42
-	-	-	34	Tinea cruris	D.H.	f	44
-	-	-	35	Haemorrhoids	K.Ri.	f	49
-	-	-	36	Tinea anogenitalis	J.Si.	f	51
-	-	-	37	Tinea anogenitalis	A.S.	f	54
-	-	-	38	Anal tinea	B.U.	f	58
-	-	-	39	Tinea anogenitalis	M.Str.	f	62
-	-	-	40	Anogenital pruritus	A.Ku.	f	39

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RESULTS FROM EPICUTAENOUS TEST

After the end of the 4-week application test

Test concentration: product 5% diluted with distilled water.

Product: Lactena Intimate Wash Lotion

24 h	48 h	72 h	No.	Condition	Name	m/f	Age
-	-	-	1	Tinea cruris	G.L.	f	34
-	-	-	2	Anal tinea	H.M.	f	48
-	-	-	3	Haemorrhoids	G.St.	f	24
-	-	-	4	Tinea genitalis	M.B.	f	34
-	-	-	5	Haemorrhoids	A.W.	f	56
-	-	-	6	Tinea genitalis	M.E.	f	45
-	-	-	7	Haemorrhoids	S.G.	f	52
-	-	-	8	Anogenital pruritus	M.Fe.	f	42
-	-	-	9	Tinea genitalis	B.No.	f	34
-	-	-	10	Haemorrhoids, Tinea genitalis	H.B.	f	49
-	-	-	11	Tinea anogenitalis	E.K.	f	43
-	-	-	12	Haemorrhoids	G.H.	f	68
-	-	-	13	Tinea genitalis	Sy.B.	f	32
-	-	-	14	Anogenital pruritus	H.Be.	f	51
-	-	-	15	Tinea anogenitalis	S.L.	f	45
-	-	-	16	Tinea anogenitalis, Haemorrhoids	D.H.	f	62
-	-	-	17	Tinea genitalis	St.P.	f	54
-	-	-	18	Tinea anogenitalis	A.H.	f	34
-	-	-	19	Anogenital pruritus	H.W.	f	68
-	-	-	20	Tinea anogenitalis	N.Ba.	f	24
-	-	-	21	Haemorrhoids	B.Gr.	f	58
-	-	-	22	Tinea anogenitalis	S.B.	f	24
-	-	-	23	Tinea inguinalis	B.R.	f	34
-	-	-	24	Anogenital pruritus	E.H.	f	72
-	-	-	25	Tinea anogenitalis	T.Schn.	f	78
-	-	-	26	Tinea genitalis	S.H.	f	38
-	-	-	27	Haemorrhoids	E.St.	f	62
-	-	-	28	Tinea anogenitalis	G.H.	f	36
-	-	-	29	Anogenital pruritus	M.B.	f	69
-	-	-	30	Tinea anogenitalis	Th.R.	f	52
-	-	-	31	Haemorrhoids	A.T.	f	70
-	-	-	32	Tinea anogenitalis	W.G.	f	46
-	-	-	33	Anogenital pruritus	B.E.	f	42
-	-	-	34	Tinea cruris	D.H.	f	44
-	-	-	35	Haemorrhoids	K.Ri.	f	49
-	-	-	36	Tinea anogenitalis	J.Si.	f	51
-	-	-	37	Tinea anogenitalis	A.S.	f	54
-	-	-	38	Anal tinea	B.U.	f	58
-	-	-	39	Tinea anogenitalis	M.Str.	f	62
-	-	-	40	Anogenital pruritus	A.Ku.	f	39

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RESULTS FROM EPICUTAENOUS TEST

After the end of the 4-week application test

Test concentration: product 1 % diluted with distilled water.

Product: Lactena Intimate Wash Lotion

24 h	48 h	72 h	No.	Condition	Name	m/f	Age
-	-	-	1	Tinea anogenitalis	B.S.	m	41
-	-	-	2	Tinea anogenitalis	St.Br.	m	47
-	-	-	3	Haemorrhoids	T.G.	m	56
-	-	-	4	Tinea anogenitalis, Haemorrhoids	H.G.	m	72
-	-	-	5	Tinea anogenitalis Haemorrhoids	W.St.	m	64
-	-	-	6	Tinea anogenitalis	H.Kr.	m	74
-	-	-	7	Tinea anogenitalis, Haemorrhoids	M.K.	m	41
-	-	-	8	Anogenital pruritus, Haemorrhoids	U.No.	m	61
-	-	-	9	Tinea genitalis, Haemorrhoids	H.Sch.	m	72
-	-	-	10	Tinea anogenitalis	G.H.	m	68

RESULTS FROM EPICUTAENOUS TEST

After the end of the 4-week application test

Test concentration: product 2% diluted with distilled water.

Product: Lactena Intimate Wash Lotion

24 h	48 h	72 h	No.	Condition	Name	m/f	Age
-	-	-	1	Tinea anogenitalis	B.S.	m	41
-	-	-	2	Tinea anogenitalis	St.Br.	m	47
-	-	-	3	Haemorrhoids	T.G.	m	56
-	-	-	4	Tinea anogenitalis, Haemorrhoids	H.G.	m	72
-	-	-	5	Tinea anogenitalis Haemorrhoids	W.St.	m	64
-	-	-	6	Tinea anogenitalis	H.Kr.	m	74
-	-	-	7	Tinea anogenitalis, Haemorrhoids	M.K.	m	41
-	-	-	8	Anogenital pruritus, Haemorrhoids	U.No.	m	61
-	-	-	9	Tinea genitalis, Haemorrhoids	H.Sch.	m	72
-	-	-	10	Tinea anogenitalis	G.H.	m	68

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RESULTS FROM EPICUTAENOUS TEST

After the end of the 4-week application test

Test concentration: product 5% diluted with distilled water.

Product: Lactena Intimate Wash Lotion

24 h	48 h	72 h	No.	Condition	Name	m/f	Age
-	-	-	1	Tinea anogenitalis	B.S.	m	41
-	-	-	2	Tinea anogenitalis	St.Br.	m	47
-	-	-	3	Haemorrhoids	T.G.	m	56
-	-	-	4	Tinea anogenitalis, Haemorrhoids	H.G.	m	72
-	-	-	5	Tinea anogenitalis Haemorrhoids	W.St.	m	64
-	-	-	6	Tinea anogenitalis	H.Kr.	m	74
-	-	-	7	Tinea anogenitalis, Haemorrhoids	M.K.	m	41
-	-	-	8	Anogenital pruritus, Haemorrhoids	U.No.	m	61
-	-	-	9	Tinea genitalis, Haemorrhoids	H.Sch.	m	72
-	-	-	10	Tinea anogenitalis	G.H.	m	68

Assessment criteria:

-	no irritation
+/-	slight or dubious erythema
+	considerable erythema
++	intense erythema and/or formation of papules
+++	cluster of papules and/or vesicles
++++	formation of blisters or necrosis

General dermatological interpretation criteria:

An allergic reaction is not just composed of erythema but also exhibits slight infiltrate. Therefore, all unclear reactions must be palpated. Often, papules and vesicles also appear. Sometimes, vesicles can fuse together to form small blisters. The reaction frequently goes far beyond the original scope of the administration of the test substance, particularly with intensive sensitivity. Occasionally, papules are formed with no erythema. Many, but not all allergy test reactions become more intense throughout the day after removing the test plaster. A very severe reaction can last for 3-4 weeks if not treated.

It is important when evaluating the results to differentiate between toxic and allergic reactions. The individual ability to react to some substances "toxically" varies significantly. Here, the evaluating dermatologist's allergologic experience and ability to judge this is particularly important. If necessary, methods have to be applied with which the irritation effect of a substance can be determined, in particular, the concentration of the test substance must be adjusted to its obligatory irritation effect.

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EVALUATION OF TEST RESULTS

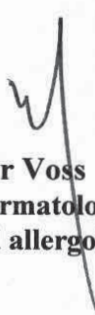
In total, 50 test persons with skin conditions including those with extremely sensitive skin (40 female, 10 male) tolerated the stated product with no problems in a 4-week application test in accordance with dermatological clinical criteria. Undesired or even pathological skin changes where the product was applied did not occur in any of the cases. The dermatologically monitored and subjectively documented tolerance was very good.

After concluding a 4-week application time, epicutaneous tests in accordance with international guidelines proved that none of the test persons became sensitised by the product during the application test. During the epicutaneous tests, none of the 50 test persons exhibited any skin changes in the test area after 24, 48 and 72 hours.

It can be concluded from this that the product will not lead to undesired skin reactions through itching or sensitising effects when applied practically on extremely sensitive skin.

In conclusion, it can be determined from a dermatological point of view that the product Lactena Intimate Wash Lotion was very well tolerated by a total of 50 test persons in a 4-week application test under clinical dermatological conditions. In terms of its dermatological skin compatibility on extremely sensitive skin, the product can be rated as very good . It is completely suitable to support care and therapy for skin conditions in the anogenital region. Furthermore, the product has a positive effect on the natural protective layer of particularly sensitive and problematic areas of the skin due to the high portion of natural whey and a small portion of washing active substances. It can be assumed that the intimate wash lotion produces an antibacterial effect on users. The evidence of this is the 8 subjects with skin conditions who were treated successfully without prescribed medication.

From a dermatological point of view, , the product throughout the entire duration of the test and the results is completely suitable for daily and preventative intimate care for bacteria or fungal infection.


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