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17489 Greifswald

Münster, 26 July 2005

Specialist-dermatological report on
clinical dermatological
APPLICATION OBSERVATION
in the case of Herpes simplex labialis

Description of preparation:

SORE AWAY

Client: bionic solution management GmbH
18 Fleischerstrasse
17489 Greifswald

Test persons: 20 subjects

Test period: from the onset of prodromal symptoms

PROBLEMS

Herpes simplex labialis is one of the most common skin diseases affecting more or less 95% of the population.

The Herpes simplex infection is a viral disease caused by the Herpes-simplex-virus type 1. The virus is transmitted via airborne infection, direct contact or smear infection. Most infected people have become infected with the virus in early youth. The disease is in no way however noticeable in the case of all infected persons. The period from infection to the disease breaking out (incubation period) is two to twelve days.

The invading viruses penetrate the upper cells of the skin and enter the respective ganglion via sensory nerves and also infect these nerves. The viruses in the mucous membrane and also in part of the infected nerve cells are eliminated during the first week. The virus can however survive unrecognizable for the immune system and therefore unassailable in the surviving nerves. These infected cells serve as a lifelong reservoir of viruses. An infection will occur as soon as the infected person's immune system has been weakened. The virus then makes its way along the nerve tract in the opposite direction towards the skin. Infection may possibly be triggered by skin irritation such as strong sunshine, injuries, burning or systematic causes such as stress, high temperature, menstruation or tumours.

The first signs of the Herpes simplex infection are tickling, burning, itching and tension and less commonly, also pain. Small blisters filled with fluid will then form. These burst after a few hours or days, dry out and leave behind scabs that heal themselves after 7-10 days. The entire process of Herpes reactivation generally takes between 10 and 14 days.

The respective parts of the skin and mucous membrane will be greatly stressed during the various stages of blister formation i.e., blister formation (vesicle phase), lesions (ulceration phase), scabs and healing.

THE STUDY

A total of 20 patients – male and female – with known lip blisters caused by Herpes simplex labialis of various descriptions took part in this study. They were initially dermatologically examined and those with normal skin were admitted to the study.

The subjects were instructed not to use any other Herpes preparations during the application study. The products were handed over with the application instructions and the request to report for immediate photograph documentation at the first Herpes symptoms.

Photographic documentation takes place digitally at the onset of symptoms or after ca. 24 hours. These are filed with the report.

Questions were asked as to the subjective assessment criteria by way of a questionnaire at the beginning and at the end of the application period.

Each test person then immediately applied the product at the first subjective symptoms of Herpes, several times if necessary.

The supervising dermatologist was able to carry out daily tests on skin conditions with objective and subjective skin changes.

Subjects

The subjects included male and females with know Herpes simplex labialis.

Exclusion criteria

- Serious or chronic skin conditions
- Serious internal disorders with deterioration expected in the near future

Dermatological tests

1. Before the application test

None of the 20 subjects showed any pathological skin changes.

2. During the application test

None of the 20 subjects during the application showed any pathological skin changes around the lips that might indicate Herpes simplex labialis. It was not necessary to interrupt the test or to carry out dermatological treatment.

3. At the end of the application test

None of the 20 subjects showed any pathological skin changes around the lips during the final pathological examination following the test.

The subjects reacted very well to the preparation in question and none of them developed any undesired skin changes.

DERMATOLOGICAL ASSESSMENT CRITERIA

1. Erythema
2. Blisters
3. Scabs
4. Swelling

SUBJECTIVE ASSESSMENT CRITERIA

1. Tension following application
2. Pain
3. Heat
4. Subjective skin sensation following application with the preparation
5. Redness

Case history questionnaire & evaluation

Application test

Please apply and activate Sore away immediately to the respective parts on appearance of the first signs of Herpes. This will generate a sensation of warmth that may border on the unpleasant. Therefore, only use Sore away on the respective areas around the edge of the lips. Please come to the institute the same day for photographing. Today's date will be taken as day 1.

1. Please describe the symptoms that normally exist before the existence of a Herpes blister. Please also classify these according to their strengths. (1 = not present, 5 = strong presence)

[] Tickling 1-----2-----3-----4-----5-
 x 1 x 3 x 12 x 3 x 1

[] Prickling 1-----2-----3-----4-----5-
 x 7 x 3 x 9 x 1 x 0

[] Itching 1-----2-----3-----4-----5-
 x 4 x 1 x 10 x 5 x 0

[] Tension 1-----2-----3-----4-----5-
 x 1 x 1 x 10 x 7 x 1

[] Swelling 1-----2-----3-----4-----5-
 x 5 x 3 x 6 x 5 x 1

[] Soreness 1-----2-----3-----4-----5-
 x 15 x 3 x 2 x 0 x 0

Please describe causative factors, as applicable that lead to Herpes in your case (e.g. sickness, sunshine, stress, etc.).

- Illness x 6
- Sunshine x 2
- Stress x 6
- Sickness x 9
- No details x 1

Application test with questionnaire
SORE AWAY

2. Please describe the symptoms that you are experiencing today. Please also classify these according to their strengths. (1 = not present, 5 = strong presence)

<input type="checkbox"/> Tickling	1-----2-----3-----4-----5-
	x 4 x 9 x 6 x 1 x 0
<input type="checkbox"/> Prickling	1-----2-----3-----4-----5-
	x 8 x 8 x 3 x 1 x 0
<input type="checkbox"/> Itching	1-----2-----3-----4-----5-
	x 8 x 5 x 5 x 1 x 1
<input type="checkbox"/> Tension	1-----2-----3-----4-----5-
	x 3 x 8 x 8 x 1 x 0
<input type="checkbox"/> Swelling	1-----2-----3-----4-----5-
	x 10 x 8 x 1 x 1 x 0
<input type="checkbox"/> Soreness	1-----2-----3-----4-----5-
	x 19 x 1 x 0 x 0 x 0

Are there factors that you can account for that may have led to Herpes on this occasion?

- Stress x 5
- Sickness x 4
- Sun x 2
- Illness x 3
- No details x 6

Now, please describe the “normal” course of a “typical” lip blister for the respective day. (Please remember: today is day 1).

3. How long does the phase normally last before the Herpes blisters occur?

- 1 day x 10
- 1-2 days x 4
- 1-3 days x 2
- 2-3 days x 1
- 2 days x 1
- 3 days x 2

Please describe the symptoms for the phase in which the blisters have not yet appeared. Please also classify these according to their overall strengths. (1 = not present, 5 = strong presence)

<input type="checkbox"/> Tickling	1-----2-----3-----4-----5-
	x 2 x 7 x 11 x 0 x 0
<input type="checkbox"/> Prickling	1-----2-----3-----4-----5-
	x 10 x 4 x 5 x 1 x 0
<input type="checkbox"/> Itching	1-----2-----3-----4-----5-
	x 5 x 5 x 7 x 3 x 0
<input type="checkbox"/> Tension	1-----2-----3-----4-----5-
	x 3 x 9 x 7 x 1 x 0
<input type="checkbox"/> Swelling	1-----2-----3-----4-----5-
	x 6 x 11 x 1 x 2 x 0
<input type="checkbox"/> Soreness	1-----2-----3-----4-----5-
	x 9 x 8 x 3 x 0 x 0

4. How long do the blisters normally remain after they have appeared (not including the scab phase, i.e. until they dry up)?

- 3 days x 8
- 2 days x 2
- 2 – 3 days x 2
- 3- 4 days x 3
- 4 days x 1
- 5 days x 1
- 6 days x 2
- 14 days x 1

Please describe the symptoms for this phase. Please also classify these according to their overall strengths. (1 = not present, 5 = strong presence)

[] Tickling	1-----2-----3-----4-----5- x 10 x 5 x 2 x 2 x 1
[] Prickling	1-----2-----3-----4-----5- x 5 x 6 x 6 x 3 x 0
[] Itching	1-----2-----3-----4-----5- x 4 x 6 x 4 x 6 x 0
[] Tension	1-----2-----3-----4-----5- x 5 x 4 x 1 x 10 x 0
[] Swelling	1-----2-----3-----4-----5- x 6 x 4 x 6 x 4 x 0
[] Soreness	1-----2-----3-----4-----5- x 9 x 5 x 3 x 3 x 0

5. How long does it normally take for the blisters to fall off after they have dried?

- 2 days x 10
- 5 days x 5
- 8 days x 1
- 3 days x 1
- 6 days x 2
- 10 days x 1

Are there also symptoms in this phase? Please also classify these according to their overall strengths. (1 = not present, 5 = strong presence)

<input type="checkbox"/> Tickling	1-----2-----3-----4-----5-	x 10	x 9	x 0	x 1	x 0
<input type="checkbox"/> Prickling	1-----2-----3-----4-----5-	x 11	x 6	x 2	x 1	x 0
<input type="checkbox"/> Itching	1-----2-----3-----4-----5-	x 10	x 8	x 2	x 0	x 0
<input type="checkbox"/> Tension	1-----2-----3-----4-----5-	x 8	x 9	x 3	x 0	x 0
<input type="checkbox"/> Swelling	1-----2-----3-----4-----5-	x 7	x 8	x 3	x 2	x 0
<input type="checkbox"/> Soreness	1-----2-----3-----4-----5-	x 11	x 7	x 2	x 0	x 0

Please confirm with your signature that you are today of the opinion that one or more Herpes blisters will develop in the afore-mentioned region. You can of course, not give a 100% prognosis to the effect that a Herpes blister will develop and as such, we only require your signature as confirmation of your assumption. There will of course be no legal repercussions.

Thank you very much for your cooperation.

Final questionnaire & evaluation

Application test

You have repeatedly applied and activated Sore away to the respective areas on the first signs of the Herpes symptoms.

Please assess the course of the condition in comparison to what you would have actually expected on appearance of the Herpes symptoms.

1. Has there been any change in the itching through using the product?

- Significant improvement x 15
- Slight improvement x 5
- No change x 0
- Slightly worse x 0
- Much worse x 0

Duration before preparation takes effect (please place a cross where applicable):

15min 30min 45min 60min 2 hrs 6 hrs 12 hrs 1 day 2 days 3 days
--|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----
x 8 x 8 x 1 x 2 x 0 x 0 x 0 x 1 x 0 x 0

2. Has there been any change in the tickling through using the product?

- Significant improvement x 18
- Slight improvement x 2
- No change x 0
- Slightly worse x 0
- Much worse x 0

Duration before preparation takes effect (please place a cross where applicable):

15min 30min 45min 60min 2 hrs 6 hrs 12 hrs 1 day 2 days 3 days
--|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----
x 8 x 8 x 3 x 0 x 0 x 0 x 0 x 1 x 0 x 0

3. Has there been any change in the burning through using the product?

- Significant improvement x 17
- Slight improvement x 3
- No change x 0
- Slightly worse x 0
- Much worse x 0

Duration before preparation takes effect (please place a cross where applicable):

15min 30min 45min 60min 2 hrs 6 hrs 12 hrs 1 day 2 days 3 days
 --|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----
 x 8 x 8 x 2 x 1 x 0 x 0 x 0 x 1 x 0 x 0

4. Has there been any change in the tension through using the product?

- Significant improvement x 15
- Slight improvement x 5
- No change x 0
- Slightly worse x 0
- Much worse x 0

Duration before preparation takes effect (please place a cross where applicable):

15min 30min 45min 60min 2 hrs 6 hrs 12 hrs 1 day 2 days 3 days
 --|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----
 x 7 x 9 x 3 x 0 x 0 x 0 x 0 x 1 x 0 x 0

5. Herpes cured after (please place a cross where applicable)

0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 days
 |-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
 x 4 x 6 x 2 x 5 x 3 x 0 x 0 x 0 x 0 x 0 x 0 x 0 x 0 x 0 x 0

6. Please give your assessment of the skin soothing effects.

- Very good (1) x 8
- Good (2) x 12
- Satisfactory (3) x 0
- Sufficient (4) x 0
- Deficient (5) x 0
- Unsatisfactory (6) x

7. Please give your assessment of the soothing effects

- Very good (1) x 8
- Good (2) x 8
- Satisfactory (3) x 4
- Sufficient (4) x 0
- Defective (5) x 0
- Unsatisfactory (6) x 0

ASSESSMENT OF TEST RESULTS

A total of 20 subjects successfully applied the stated preparation in the application test according to dermatological clinical criteria. There were no cases of undesired or even pathological skin changes around the lips

The subjects have provided assurance that due to the application of Sore away, there have been no developments of Herpes labialis as they have experienced in the past.

**It can finally be said, from a dermatological standpoint
and regarding this application study of 20 subjects that the product to be tested, Sore away
according to application under dermatological clinical criteria was endured very well and
according to statements by subjects, prevented the development of the Herpes-simplex-virus.**

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