eurofins | Dermatest

CLINICAL TRIAL REPORT

Clinical Evaluation of Moisturizing, Sebo-Regulating and Non-Comedogenic Effects of *Sebuma* Durable Shine Control Moisturizing and Repairing Cream Gel on Dry and Acne-Prone Skin

STUDY DETAIL:

Study Type	Clinical Trial
Study Center	20 King Street, Rockdale NSW 2216 Australia
Study Number	020-GVR-LLO-19-11
Study Start Date	August, 2019
Actual Study Completion Date	November, 2019

CLIENT INFORMATION:

Client Name	Pars Hayan Laboratories
Client address	No. 54, West Atefi Ave, Nelson Mandela Blvd, Tehran, Iran.
Samples Received on	July 2019

STUDY DESIGN:

Official Title	A 4-week, Randomized Study Analyzing the Clinical Efficacy of **"*Sebuma* Durable Shine Control Moisturizing and Repairing Cream Gel"** (Hyaluronic Acid, Ceramide (III), Capryloyl Glycine, Salicylic Acid, Glycolic Acid, Zinc Gluconate, Lactic Acid, Niacinamide) in Patients with Dry and Acne- Prone Skin
Actual Enrollment	16 participants
Primary Purpose	Treatment
Ages Eligible for Study	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study	All
Studied product	*Sebuma* Durable Shine Control Moisturizing and Repairing Cream Gel
Active Ingredients in Product	**Primary Actives:** Hyaluronic Acid Ceramide (III) Capryloyl Glycine Salicylic Acid Glycolic Acid Zinc Gluconate Lactic Acid Niacinamide **Secondary Active:** Aloe Vera Gel
Application Method	Qualified subjects will apply the product twice a day, morning and evening, on the perfectly cleansed and dried skin and massage it gently until absorbed. Subjects apply the product for a period of 4 weeks and will be required to return to the doctor's office for up to 4 visits.

eurofins
Dermatest Laboratory
20 King Street, Rockdale NSW 2216 Australia
Tel: +61 2 9566 3825 Fax: +61 2 95663861

CRITERIA:

To be included in the study, participants have the following criteria:

- Male or female subjects in general good health 18 years of age or older
- Participant provision of a signed and dated informed consent document indicating that the participant has been informed of all pertinent aspects of the study before any assessment is performed.
- A participant who is willing and able to comply with scheduled visits, the product application schedule, the Lifestyle Considerations, and other study procedures which includes: a) to remove facial make-up at the screening visit to allow visual assessments; b) using other skin-care products is not permitted including but not limited to: leave-on cosmetics, moisturizers, lotions, creams, sunscreens, soaps, cleansing, exfoliation products, etc. on their face, other than the standard soap and study product(s) provided; c) at all post baseline study visit days, participants must cleanse their face with the standard soap and then apply the test product (s) approximately 10-16 hours before each study appointment (i.e. evening before); d) no use of any product on the face, including the standard soap and test product, within 10 hours of all instrumental measurements on visit days (no showering/bathing permitted with soaps/shampoo within this period) will be permitted.
- A participant in good general and mental health with, in the opinion of the investigator or medically qualified designee (if the investigator is not suitably qualified), no clinically significant/relevant abnormalities in medical history or upon dermatologist examination, or condition, that would impact the participant's safety, wellbeing or the outcome of the study, if they were to participate in the study, or affect the individual's ability to understand and follow study procedures and requirements.
- A participant with an overall dryness assessment total score of ≥3 for each side of the face at screening visit (Visit 1). With no more than 0.5-unit score difference between each side of the face. Including an examiner score of at ≥ 1 (slight) for the roughness parameter.

eurofins
Dermatest Laboratory
20 King Street, Rockdale NSW 2216 Australia
Tel: +61 2 9566 3825 Fax: +61 2 95663361

EXCLUSION CRITERIA:

To be included in the study, participants should not have the following criteria:

- A participant who has participated in other studies (including non-medicinal studies) involving investigational product within 30 days prior to study entry and/or during study participation.
- A female participant who is pregnant or breastfeeding.
- A participant with known or suspected intolerance or hypersensitivity to the study materials (or closely related compounds) or any of their stated ingredients.
- A participant with current or recent (within 6 months before the start of the study) history of atopic lesions and/or eczema.
- A participant with a history of allergic reactions to topical-use products, cosmetics or medications or their ingredients.
- A participant with any history of significant diseases or medical conditions known to alter skin appearance or physiologic response (e.g. Type 2 diabetes) which could, in the opinion of the Investigator, preclude topical application of the investigational products and/or interfere with the evaluation of the test site reaction.
- A participant presenting open sores, pimples, or cysts at the application site.
- A participant currently using any medication which in the opinion of the investigator, may affect the evaluation of the investigational product, or place the participant at undue risk
- A participant who has used any of the following topical or systemic medications up to 1 month before the screening visit or intends to use during the study period: immuno-suppressants, antihistamines, non-steroidal anti-inflammatory drugs (NSAIDS), and corticosteroids.
- A participant who has used oral or topical treatment with vitamin A acid and/or its derivatives up to 1 month before the screening visit or intends to use during the study period.
- A participant with any skin marks on the face that might interfere with the evaluation of possible skin reactions (e.g. pigmentation disorders, vascular malformations, scars, tattoos, excessive hair, numerous freckles).
- A participant who is unwilling to abstain from smoking tobacco or using any other nicotine containing products.
- A participant with moles, tattoos, scars, hairs, etc. at the test areas if it is likely that they could affect the assessments.
- A participant who has used self-tanning products on the test areas within 2 weeks prior to the screening visit.
- A participant who intends to expose their skin to natural or artificial ultraviolet
- A participant with any participant self-assessed or dermatologist dryness parameter score 4 (very severe) on the test areas of the lower legs or face.

eurofins
Dermatest Laboratory
20 King Street, Rockdale NSW 2216 Australia
Tel: +61 2 9566 3825 Fax: +61 2 95663861

PROCEDURE AND EXPERIMENT:

Moisturizing & Repairing

Technique:

The hydrating effect of a product can be evaluated over short or long term. Skin hydration test is performed using a Corneometer and is usually compared to the baseline (untreated) skin. Test subjects are pre-screened and those identified as having dry skin types, are used in the test. Skin moisture measurement is performed using instruments which are designed to measure the electrical conductivity of the skin.

Mechanism:

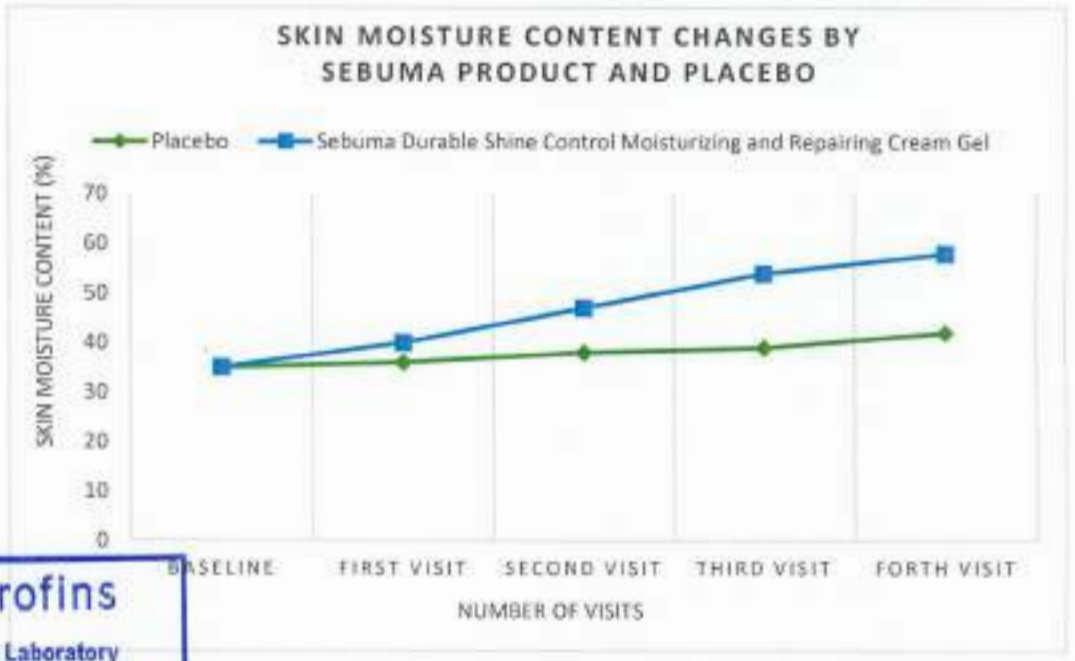
As the water content of the skin increases, the ability to conduct electrical current is also increased. The hand held probe of the instrument is held against the skin and a very low intensity electrical current passes between two electrodes in contact with the skin surface. The electrical resistance is digitally indicated - high resistance = low moisture and low resistance = high moisture.

Number of Test Subjects:

When tested on test subjects with dry skin conditions, an effective moisturizer should provide at least 20 to 30% improvement. Provided there is not a high variability between individual test participants, A 10-person study should show significant results.

Procedure and Result:

16 subjects were randomly divided into two groups (Sebuma group, n = 10; placebo group, n = 6). The skin moisture content was measured for all subjects using a Corneometer and the data were presented as mean values. Figure 1 demonstrates the mean value of skin moisture content in 10 participants after using *Sebuma* durable shine control moisturizing and repairing cream gel compared to 6 participants after using placebo. **As it is shown, the test product provides more than 60% improvement in skin moisture and hydration which subsequently contribute to accelerate skin barrier repair and is efficient enough to be considered as a product with both moisturizing and repairing effect.**



eurofins
Dermatest Laboratory
20 King Street, Rockdale NSV 2216 Australia
Tel: +61 2 9566 3825 Fax: +61 2 95663861

Anti-Sebum & Sebum Control

Technique:

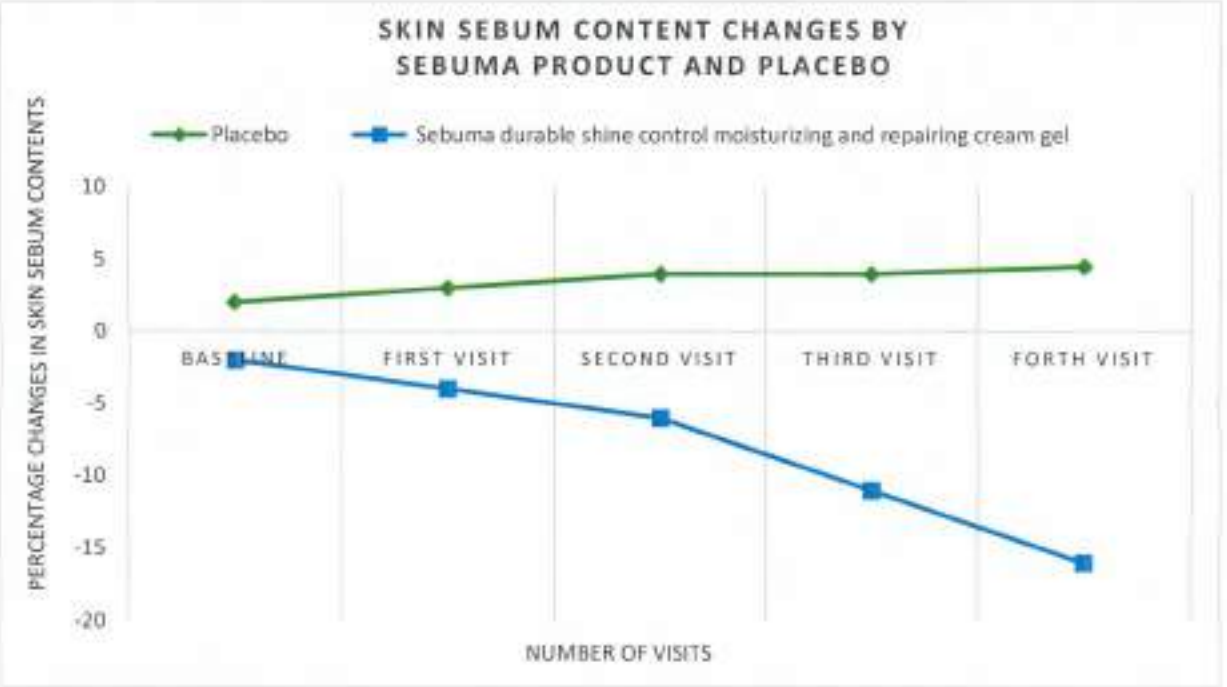
The sebaceous gland activity and the sebum production can be determined using the Sebumeter. Both the sebum levels and the seborrheic activity are assessed by image analysis.

Mechanism:

Measurements are based on greasy spot photometry. Samples are taken by applying a mat tape which is dispensed from a Sebumeter dispenser. The sample is then immediately inserted into the reader and the opacity is measured by a photocell. Baseline is determined on the same or an adjoining area just prior to commencement of the study.

Procedure and Result:

16 subjects were randomly divided into two groups (Sebuma group, n = 10; placebo group, n = 6). The percentage changes in skin sebum contents was measured for all subjects using a Sebumeter and the data were presented as mean values. Figure 2 demonstrates the mean value of percentage changes in skin sebum content in 10 participants after using *Sebuma* durable shine control moisturizing and repairing cream gel compared to 6 participants after using placebo. In this clinical study a slightly increased sebum content was observed by the placebo product, but in case of test product there was a significant decrease observed in skin sebum content throughout the study period. Therefore, it can be concluded that the sebum level of the skin was regulated and reduced after using the product.



Non-Comedogenic Test

Technique:

A non-comedogenic test evaluates the skin condition before and after of product usage. The evaluator counts the number of comedones and blackheads on the forehead, cheeks and chin.

Alternatively, a non-comedogenic claim can be assessed via a microscopic examination of the skin after application of patches containing the product.

Participants	Number of Comedones Before Applying the Product	Number of Comedones After Applying the Product	Result
Patient 1	3	2	Improved
Patient 2	4	1	Improved
Patient 3	8	4	Improved
Patient 4	13	8	Improved
Patient 5	2	2	Insignificant Change
Patient 6	8	7	Improved
Patient 7	4	4	Insignificant Change
Patient 8	5	1	Improved
Patient 9	3	1	Improved
Patient 10	6	4	Improved
Patient 11	5	3	Improved
Patient 12	10	6	Improved
Patient 13	11	5	Improved
Patient 14	6	6	Insignificant Change
Patient 15	2	0	Improved
Patient 16	1	1	Insignificant Change

Result and Conclusion:

Sebum secretion is intended to be one of the major and initiating factors involved in the formation, occurrence and severity of acne lesions and comedones. The correlation between sebum output and the pathophysiology of acne demonstrates that a high sebum secretion rate is a decisive factor in inflammatory acne lesions and comedones. This study was conducted under the supervision of a dermatologist using a microscopic examination of the skin before and after applying the test product. Data reported in this clinical study clearly indicate that 12 patients out of 16 (almost 75%) have shown improvement in acne appearance as a result of decline observed in skin sebum content throughout the study period. **In conclusion the test product is designed to regulate and reduce skin sebum content which may further minimize the comedogenicity and irritation potential of the product, thus it can be considered as a non-comedogenic cream gel.**

eurofins
Dermatest Laboratory
20 King Street, Rockdale NSW 2216 Australia
Tel: +61 2 9566 3825 Fax: +61 2 95663861