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# CLINICAL TRIAL REPORT

## Anti-Acne Efficacy Evaluation of *Sebuma* Anti Acne Back & Body Spray on Subjects with Mild to Severe Acne

**STUDY DETAIL:**

| | |
|---|---|
| **Study Type** | Clinical Trial |
| **Study Center** | 20 King Street, Rockdale NSW 2216 Australia |
| **Study Number** | 412-STR-KJU-19-08 |
| **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 |

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**STUDY DESIGN:**

| | |
|---|---|
| **Official Title** | A 4-week, Randomized Study Analyzing the Clinical Efficacy of "***Sebuma* Anti Acne Back & Body Spray**" (Salicylic Acid 2%, Glycolic Acid, Piroctone Olamine, Spiraea Ulmarina Extract, Niacinamide) in Patients with Mild to Severe Acne |
| **Actual Enrollment** | 8 participants |
| **Primary Purpose** | Treatment |
| **Ages Eligible for Study** | 18 Years to 35 Years (Adult) |
| **Sexes Eligible for Study** | All |
| **Studied product** | *Sebuma* Anti Acne Back & Body Spray |
| **Active Ingredients in Product** | **Primary Actives:**<br>Salicylic Acid 2%<br>Glycolic Acid<br>Piroctone Olamine<br>Spiraea Ulmarina Extract<br>Niacinamide<br><br>**Secondary Actives:**<br>Licorice Extract<br>Chamomile Extract<br>Green Tea Extract<br>Burdock Extract |
| **Application Method** | Qualified subjects will cover the entire affected area with a thin layer one to three times daily. Start with one application daily, then gradually increase to three times daily if needed. 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. |

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**CRITERIA:**

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

- Healthy male or female subjects who are 18 to 35 years of age.
- Subjects are in good health and are free of any other skin disorders that may interfere with acne study assessments.
- Subjects have the willingness and ability to understand and provide informed assent/consent to participate in the study and are able to communicate with the investigator. Subjects are willing and able to follow all study directions and to commit to all follow-up visits for the duration of the study. In addition, subjects must be willing to accept the restrictions of the study.
- A minimum of 5 inflammatory lesions (papules and pustules) and a minimum of 5 non-inflammatory lesions (open comedones and closed comedones on back and body. At least one inflammatory lesion should be measured no smaller than 2 mm in diameter and should be visible in images taken with digital imaging station.
- Ongoing oral medications (other than those specifically for acne) are acceptable provided subjects are on a stable regimen throughout the study and provided the medications are determined likely to not interfere with study assessments.
- Subjects will not use medicated cosmetics and/or soaps (including soaps containing antibacterial agents such as benzoyl peroxide, keratolytic agents such as salicylic acid, skin fresheners/astringents) for the duration of the study.
- Subjects who agree not use any other acne treatment (including prescription and non-prescription medications) on the test site for the duration of the study.

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**EXCLUSION CRITERIA:**

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

- Subjects with no inflammatory acne.
- Subjects with any acne cysts or nodules.
- Subjects with acne conglobate, acne fulminans, secondary acne (e.g. Chloracne, drug-induced acne), or any acne requiring systemic treatment.
- Subjects with excessive hair that may interfere with study assessments.
- Subjects with other skin disorders that may interfere with study assessments.
- Subjects with a history of skin cancer or actinic keratosis.
- Subjects who have used tanning devices within one week prior to baseline study visit.
- Subjects who have applied any topical products (e.g. emollients, sunscreens) at least one hour prior to study assessments.
- Use of hormonal oral contraceptives for acne control or for less than 6 months prior to study baseline.
- Subjects with known allergies, a history of allergy or sensitivity to salicylic acid, or any of the test article components.
- Subjects using topical or systemic medication within 14 days before the study entry, which could interfere with study assessments. This includes but is not limited to the following: anti-inflammatory drugs (e.g. topical and systemic corticosteroids and systemic antihistamines), anti-acne drugs, topical and oral retinoids, topical antibacterial agents and any immunosuppressive drugs. Ongoing oral medications not expected to interfere with study assessments are allowed if the subject is on a stable regimen.
- Subjects who are currently enrolled in another clinical investigation or have been enrolled in an acne trial within a period of 30 days prior to enrollment in this study.
- Subjects who are pregnant or nursing.
- Subjects who require electrolysis, waxing, or depilatories on the body during conduct of the study.
- Subjects viewed by the investigator as not being able to complete the study.

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**PROCEDURE AND EXPERIMENT:**

Investigator's assessment of subject's acne condition using a score of 0 (best) and 5 (worst) based on lesion counting technique of Cook's photographic method.

Lesion counting involves recording the number of each type of acne lesion and determining the overall severity. It is defined as the total number of comedones and inflammatory lesions.

**SCORE SYSTEM BASED ON COOK'S PHOTOGRAPHIC METHOD:**

**Studied Area: Back of the Body**

| Condition | Score | Description |
|---|---|---|
| Clear | 0 | The comedones are treated |
| Very Mild | 1 | Easily recognizable; less than half of the back is involved. |
| Mild | 2 | |
| Moderate | 3 | More than half of the back is involved. |
| Severe | 4 | The whole affected area is involved. |
| Very Severe | 5 | |

| participants | First Condition | First Visit | Second Visit | Third Visit | Forth Visit | Result |
|---|---|---|---|---|---|---|
| 1 | Moderate | Moderate Score: 3 | Mild Score: 2 | Mild Score: 2 | Very Mild Score: 1 | Improved |
| 2 | Severe | Severe Score: 4 | Moderate Score: 3 | Mild Score: 2 | Clear | 0 |
| 3 | Very Severe | Severe Score: 4 | Moderate Score: 3 | Moderate Score: 3 | Mild Score: 2 | Improved |
| 4 | Very Mild | Very Mild Score: 1 | Clear | | | 0 |
| 5 | Severe | Severe Score: 4 | Mild Score: 2 | Vary Mild Score: 1 | Clear | 0 |
| 6 | Mild | Very Mild Score: 1 | Very Mild Score: 1 | Clear | | 0 |
| 7 | Moderate | Mild Score: 2 | Very Mild Score: 1 | Clear | | 0 |
| 8 | Very Severe | Severe Score: 4 | Moderate Score: 3 | Very Mild Score: 1 | Clear | 0 |

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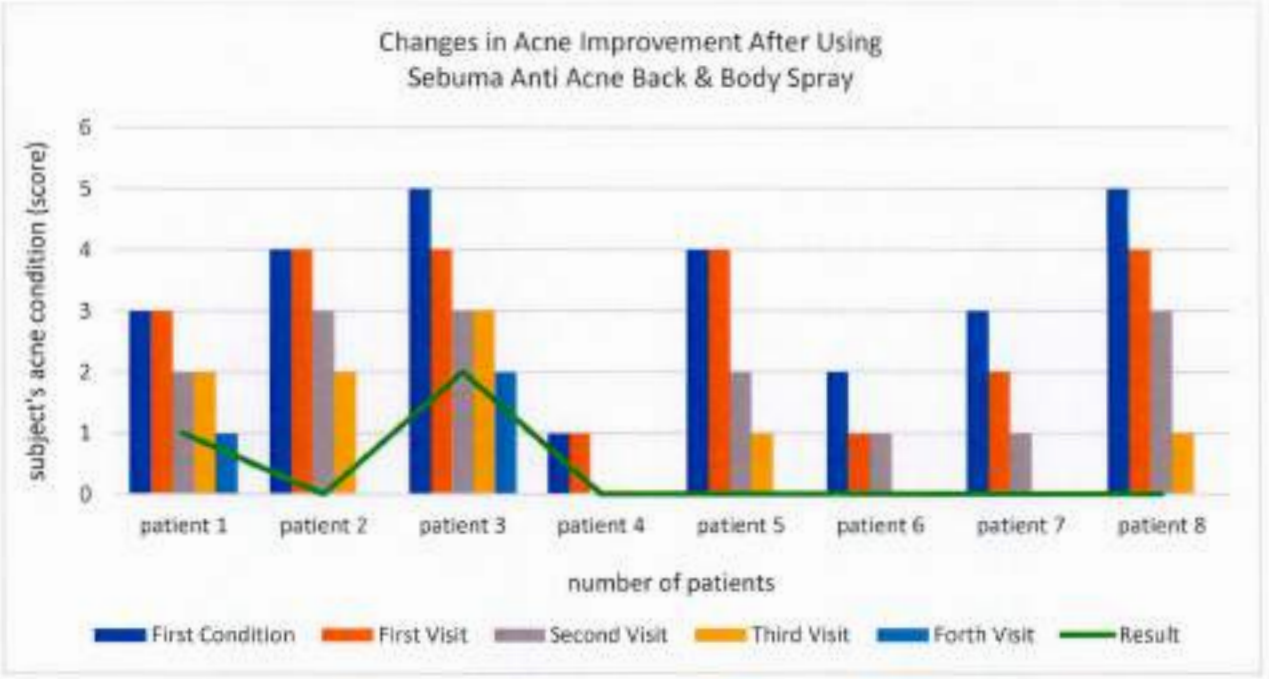


**Result and Conclusion:**

This study evaluated the efficacy of a 4-week treatment using combination of Salicylic Acid 2%, Glycolic Acid, Piroctone Olamine, Spiraea Ulmarina Extract and Niacinamide in patients with mild to severe body acne. Salicylic Acid is an effective treatment for blackhead and whitehead types of acne while Glycolic Acid makes a significant difference in acne removal by gently exfoliating the skin and removing excess dead skin cells. The results of clinical study under dermatological control of *Sebuma* Anti Acne Back & Body Spray demonstrate remarkable reduction in the total lesion number and size of acne and inflammatory lesions. Moreover, it effectively eliminates blemishes and imperfections compared to baseline which lead to the improvement of overall body skin condition.

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