

**CLINICAL TRIAL REPORT****Clinical Evaluation of *Sebuma* Rapid Acne Spot Removal Gel for the Treatment of Acne Scarring**

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**STUDY DETAIL:**

Study Type	Clinical Trial
Study Center	20 King Street, Rockdale NSW 2216 Australia
Study Number	920-ABQ-AAW-19-09
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:**

<b>Official Title</b>	A 2-Month, Randomized Study Analyzing the Clinical Efficacy of " <b>Sebuma Rapid Acne Spot Removal Gel</b> " (Salicylic Acid 2%, Sepicontrol A5, Niacinamide, Zinc Gluconate) in Patients with Acne Scar
<b>Actual Enrollment</b>	10 participants
<b>Primary Purpose</b>	Treatment
<b>Ages Eligible for Study</b>	18 Years to 35 Years (Adult)
<b>Sexes Eligible for Study</b>	All
<b>Studied product</b>	<i>Sebuma</i> Rapid Acne Spot Removal Gel
<b>Active Ingredients in Product</b>	<b>Primary Actives:</b> Salicylic Acid 2% Sepicontrol A5 (Mixture of Capryloyl Glycine (25%), Hexylene Glycol (20%), Sarcosine (7%) & Cinnamomum Zeylanicum Bark Extract (3%) & water (to 100)) Niacinamide Zinc Gluconate  <b>Secondary Actives:</b> Hamamelis Leaf Extract Licorice Extract Aloe Vera Gel
<b>Application Method</b>	Qualified subjects will cleanse the skin thoroughly before using the product. Then apply a thin layer of product directly to affected area one to three times daily. Subjects apply the product for a period of 2 months and will be required to return to the doctor's office for up to 5 visits.

## 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 scarring 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.
- Ongoing oral medications (other than those specifically for acne scarring) 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 scarring treatment (including prescription and non-prescription medications) on the test site for the duration of the study.

## EXCLUSION CRITERIA:

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

- Subjects who have had a chemical peel in the past 3 months
- Subjects with other skin disorders that may interfere with study assessments.
- Subjects with excessive hair that may interfere with study assessments.
- Subjects with a history of skin cancer
- Subjects who have used a prescribed retinoid in the past 3 months
- Subjects with a history of skin disorders, such as keloids, abnormal wound healing, as well as very dry and fragile skin.
- Subjects with a history of abnormal scarring
- 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.
- Subjects with known allergies, a history of allergy or sensitivity to salicylic acid, or any of the test article components.
- Subjects who are currently enrolled in another clinical investigation within a period of 30 days prior to enrollment in this study.
- Subjects who are pregnant or lactating.
- Subjects who require electrolysis, waxing, or depilatories on the skin during conduct of the study.
- Subjects viewed by the investigator as not being able to complete the study.
- Treating over tattoo or permanent makeup.



## PROCEDURE AND EXPERIMENT:

Changes in acne scarring in 10 patients during 2 months compared to baseline as assessed by qualified evaluators by photographic assessment utilizing a 5-point Global Aesthetic Improvement Scale (GAIS) for acne scarring.

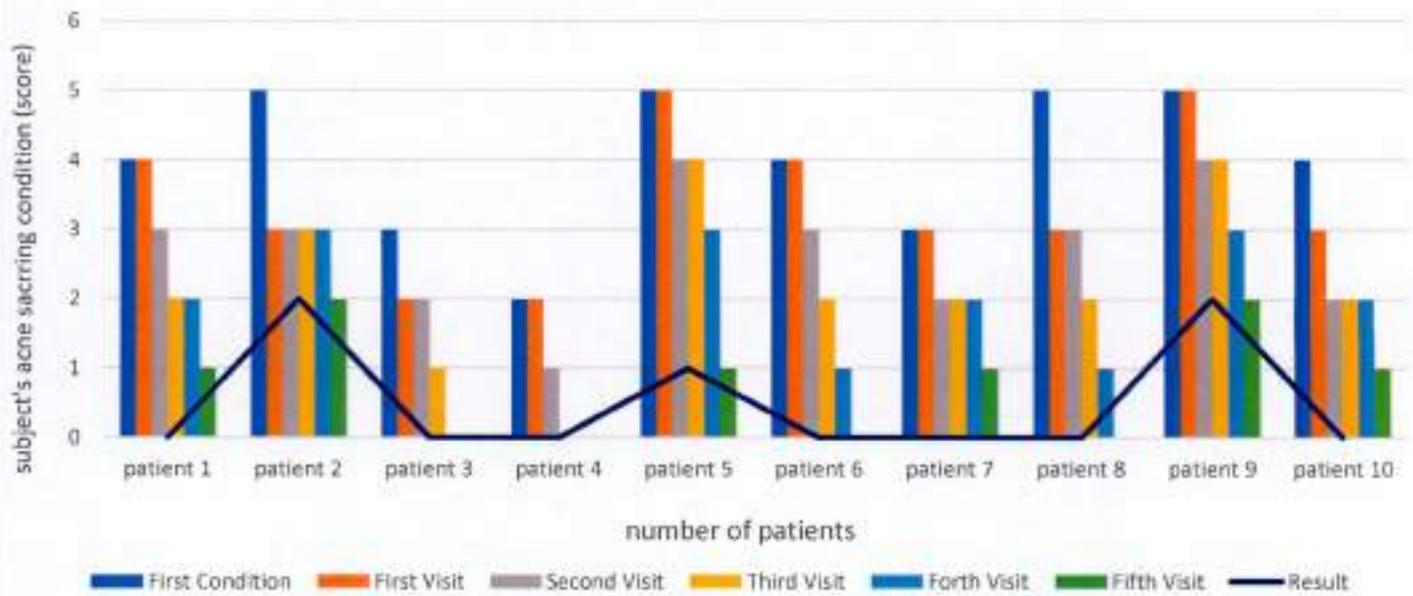
## SCORE SYSTEM BASED ON GAIS:

Score	Degree	Description
1	Outstanding Improvement	Excellent Experiment Result.
2	Very Improved	Marked Improvement in Appearance from Initial Condition, But Not Completely Excellent. A Touch-up Would Improve the Result.
3	Improved Condition	Obvious Improvement in Appearance from Initial Condition, But Retreatment Indicated.
4	Unaltered Condition	Appearance Essentially the Same as the Initial Condition.
5	Worsened Condition	Appearance Worse than the Initial Condition.

participants	First Condition	First Visit	Second Visit	Third Visit	Forth Visit	Fifth Visit	Result
Patient 1	4	4	3	2	2	1	Clear
Patient 2	5	3	3	3	3	2	Improved
Patient 3	3	2	2	1			Clear
Patient 4	2	2	1				Clear
Patient 5	5	5	4	4	3	1	Improved
Patient 6	4	4	3	2	1		Clear
Patient 7	3	3	2	2	2	1	Clear
Patient 8	5	3	3	2	1		Clear
Patient 9	5	5	4	4	3	2	Improved
Patient 10	4	3	2	2	2	1	Clear



Changes in Acne Scarring After Using  
*Sebuma* Rapid Acne Spot Removal Gel



### Result and Conclusion:

This study evaluated the efficacy of a 2-month treatment using combination of Salicylic Acid 2%, Sepicontrol A5, Niacinamide and Zinc Gluconate in patients with visible signs of blemishes and also post-acne marks. Salicylic Acid is one of the useful peeling agents for the treatment of acne scars. In addition, Sepicontrol A5 is proven to regulate sebum production and reduce the comedogenicity of the overall formulation. The results of clinical study under dermatological control of *Sebuma* Rapid Acne Spot Removal Gel illustrate efficient elimination of facial acne scars and spots. It effectively reduces pimple redness and swelling compared to baseline which contribute to the improvement in uniformity of skin tone and texture. **Moreover, the test product decreases the possibility of comedogenicity, acnegenicity and irritancy, thus it can be considered as a non-comedogenic gel.**

