

Demonstrated Tolerability and Clinical Efficacy of Salicylic Acid Formulations as a First Line of Defense for Acne

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Key Findings: The routine use of salicylic acid (SA) containing products recommended for the management of acne significantly* reduced blemish appearance, the size of breakouts, blemish redness, and associated flakiness/dryness in acne prone and/or sensitive skin subjects. In addition, the impact of product use on the skin barrier was evaluated after 28 days. The use of a salicylic acid acne cleanser or salicylic acid serum was associated with a statistically significant average decrease* in TEWL, indicative of improved skin water barrier integrity. The use of a 2% salicylic acid cleanser, 2% salicylic acid serum, or 1.8% salicylic acid spot treatment was well tolerated in subjects 8-18 years of age and did not exhibit a potential for irritation or hypersensitivity during in-use conditions.

Methods:

Efficacy Studies Overview

2% SA Cleanser

- 28-day effectiveness
- Visual expert grading
- TEWL (Transepidermal water loss)
 - DermaLab Evaporimeter

20

12

N=32

Age	18-43
White	15
Hispanic	14
African American	1
Mixed/Other	2

2% SA Serum

- 7-day effectiveness
- Visual expert grading
- TEWL (Transepidermal water loss)
 - DermaLab Evaporimeter

21

10

N=31

Age	18-43
White	15
Hispanic	13
African American	2
Mixed/Other	1

1.8% SA Spot Treatment

- 24-hour effectiveness
- Visual expert grading

23

7

N=30

Age	18-45
White	11
Hispanic	16
African American	2
Mixed/Other	1

Every Study Followed a Standardized Approach

- 7-day washout with a daily wash procedure which was standardized with the use of a lab-issued gentle facial cleanser.
 - Only subjects who abstained from using any anti-acne, exfoliating, anti-aging, sun-protecting or moisturizing products throughout the entire study period including the washout phase were recruited for participation.
- Limitation of sun exposure and wearing of sun protective clothing whenever possible.
- Key inclusion criteria were individuals with self-assessed oily, combination or acne-prone skin and confirmed by the Investigator. Also, individuals with presence of mild to moderate acne, including visible blemishes, blackheads, or clogged pores, as confirmed by a skin assessment.
- Participants were also instructed to keep a log noting the date and time of each application together with any subjective comments relating to product use.

Methods:

Safety in Use Studies – Children and Teens

2% Salicylic Acid Cleanser

20

14

N=34

Age	12 to 18
White	19
Hispanic	7
African American	4
Mixed/Other	4

2% Salicylic Acid Serum

19

13

N=32

Age	12 to 18
White	20
Hispanic	6
African American	4
Mixed/Other	2

1.8% Salicylic Acid Spot Treatment

19

10

N=29

Age	12 to 18
White	7
Hispanic	12
African American	3
Mixed/Other	7

Findings:

A Significant Average Decrease In Transepidermal Water Loss (TEWL)

Salicylic Acid Cleanser TEWL, N=32

11.2

-7.32*

10.4

g/m² h

Baseline

Day 28

Salicylic Acid Serum TEWL, N=31

10.8

-12.4%*

9.49

g/m² h

Baseline

Day 7

Design: 4-week (SA Cleanser), 7-day (SA Serum), computerized Evaporimeter using Dermalab System (cyberDERM, Inc.) Baseline and 28 days (SA Cleanser), Baseline and 7-day (SA Serum).

Application: Twice daily, 2% SA cleanser use (left) or once daily, 2% SA serum application (right)

2% Salicylic Acid Acne Cleanser with glycerin, super humectant Aquaxy™, niacinamide, coconut-based cleansing agents

Significant Mean Reductions of Common Acne Related Skin Complaints Were Seen as Early as 7 Days (N=32)

Baseline

Day 7

Day 28

Blemish Appearance

Size of Breakouts

Blemish Redness

Flaking/Dryness Appearance

1.72

1.72

1.47

0.75

0.31

0.34

0.06

0

-25.5%*

-25.5%*

-48.9%*

-78.7%*

-70.9%*

-81.8%*

-100.%*

Design: 4-week visual expert grading (5-point scale) at 7 and 28 days.

Application: Twice daily.

2% Salicylic Acid Acne Serum with squalane, exfoliating willow bark, colloidal oatmeal

Significant Mean Reductions of Common Acne Related Skin Complaints Were Seen by Day 3 (N=31)

Baseline

Day 3

Day 7

Blemish Appearance

Size of Breakouts

Blemish Redness

Flaking/Dryness Appearance

1.74

1.71

1.39

0.06

1.35

1.48

1.03

0

1

1.06

0.65

0

0

-22.2%*

-13.2%

-25.6%*

-100%*

-42.6%*

-37.7%*

-53.5%*

-100%*

Design: Efficacy of a facial serum when tested over a 7-day period using visual expert grading (5-point scale) at 3 and 7 days. Skin barrier integrity was determined instrumentally using TEWL measurements via DermaLab Evaporimeter®. **Application:** Once daily.

1.8% Salicylic Acid Spot Treatment

Significant Mean Reductions of Common Acne Related Skin Complaints (N=30)

Baseline

8 hours

24 Hours

Size of Breakouts

Blemish Redness

2.17

2.03

1.43

1.37

1.17

0.87

-33.9%*

-32.8%*

-46.2%*

-57.4%*

Design: Evaluate the efficacy of a topically applied acne spot treatment when tested over a 24-hour period. Effectiveness of the test product was evaluated objectively via visual expert grading. **Application:** Small amount of spot treatment directly to the blemish, surrounding skin, and pore area. Let it dry for 2 minutes. (8 hours based on 1 application, 24 hour based on 3 applications)

Findings:

Routine Use of a 2% Salicylic Acid Cleanser, 2% Salicylic Acid Serum, or 1.8% Salicylic Acid Acne Spot Treatment Was Well Tolerated in Pediatric Subjects 12-18 Years of Age With no Clinically Meaningful Changes in Erythema, Occurrence of Edema, or Dryness.

Percent of Assessments, N=34 (Cleanser)

Dryness Baseline

Dryness 4 Weeks

Edema Baseline

Edema 4 Weeks

Erythema Baseline

Erythema 4 Weeks

100.0

100.0

100.0

100.0

75.0

69.1

11.8

19.1

13.2

10.3

1.5

Percent of Assessments, N=32 (Serum)

Dryness Baseline

Dryness 4 Weeks

Edema Baseline

Edema 4 Weeks

Erythema Baseline

Erythema 4 Weeks

93.8

93.8

100.0

100.0

67.2

73.4

18.8

20.3

14.1

8.3

1.1

Percent of Assessments, N=29 (Spot Treatment)

Dryness Baseline

Dryness 4 Weeks

Edema Baseline

Edema 4 Weeks

Erythema Baseline

Erythema 4 Weeks

84.5

84.5

100.0

94.8

72.4

77.6

15.5

15.5

19.0

13.8

8.6

8.6

0% 20% 40% 60% 80% 100%

None Barely Perceptible Mild Moderate Marked Severe

Facial assessments are side specific and treated as independent observations.