

# Tolerance of a Low-Level Blue and Red Light Therapy Acne Mask in Acne Patients with Sensitive Skin

**Dara Miller<sup>1</sup>, Michael J. Cohen<sup>1</sup>, Adegboyega Adenaike<sup>1</sup>, Julie Biron<sup>2</sup>, Michael H. Gold, MD<sup>2</sup>**

<sup>1</sup>Johnson & Johnson Consumer, Inc., Skillman, NJ USA

<sup>2</sup>Tennessee Clinical Research Center, Nashville, TN USA

# Background & Study Design

## Abstract

- Acne and sensitive skin are often associated, due to the involvement of an impaired skin barrier in both conditions, which can be further aggravated by certain topical acne treatments. Patients are especially aware of this interplay due to the sensory nature of these conditions, with the treatment-induced signs and symptoms of irritation leading to poor patient compliance and ultimately dissatisfaction with treatment outcomes from topical ingredients. Therefore, a non-topical, chemical-free treatment that is well-tolerated by patients with self-perceived sensitive skin for use in the treatment of acne is highly desirable.
- Recent research has confirmed that low-level blue and red light therapy reduces inflammatory and non-inflammatory lesions in mild-to-moderate acne by targeting acne-causing bacteria and promoting anti-inflammatory activity, respectively.
- A 4-week, open-label clinical study was conducted to evaluate the tolerance of a novel low-level blue and red light technology in mild-to-moderate acne and self-perceived sensitive skin. This therapy was found to be well-tolerated and gentle in sensitive facial skin with no statistically significant increases in objective or subjective tolerance measures, and no treatment-related adverse events. In addition, subjects agreed that the light therapy was comfortable and gentle to their sensitive skin.
- This clinical study confirms that a new low-level blue and red light therapy technology provides a chemical and UV-free treatment option for mild-to-moderate acne patients with sensitive skin, including those who have experienced sensitivity to topical acne treatments in the past.

**Study Design:** 4-week, single-center, open-label study. Mild cleanser used twice per day, and once daily treatment with the light therapy device, per the label instructions, each night

**Sample Size:** 45 subjects enrolled & included in Full Analysis Set (FAS), 43 subjects completed

**Endpoints:** Investigator and subject evaluations for tolerance, adverse event monitoring

Study Population	
Gender	Males and Females
Age	12 – 40 yrs. old
Acne Severity	Mild to moderate acne (Investigator's Global Acne assessment)
Skin Sensitivity	Subjects were enrolled if they met both criteria: <ul style="list-style-type: none"><li>• identified as having sensitive skin Most or All of the time</li><li>• responded YES to 1 additional Sensitive Skin Questionnaire attribute</li></ul>
Fitzpatrick Skin Type	FST I-VI were eligible for enrollment Completed: FST II = 33.3%      FST III = 24.4% FST IV = 13.3%    FST V = 8.8% FST VI = 20%

# Sensitive Skin Profile & Investigator & Subject Tolerability Evaluations

Sensitive Skin Questionnaire Baseline Characteristics		
	N	(%)
Do you consider your facial skin to be sensitive? <i>Most of the time</i>	26	(57.8)
<i>All of the time</i>	19	(42.2)
In the past, have you ever experienced skin irritation when using topical acne treatments? <b>YES</b>	38	(84.4)
In the past, have you ever stopped using a topical acne treatment due to skin irritation? <b>YES</b>	25	(55.6)
Have you ever been told by a professional that you have sensitive skin on your face? <b>YES</b>	15	(33.3)
When purchasing skincare products do you look for products labelled "for sensitive skin" or similar? <b>YES</b>	42	(93.3)

Statistics for Cutaneous Tolerability Evaluation			
Mean score (SD) change vs. Baseline (mean)			
Attribute	Baseline	Week 2	Week 4
<b>Investigator-Evaluated Tolerance</b>			
Erythema	0.09 (0.29) N/A	0.00 (0.00) -0.09	0.02 (0.15) -0.07
Scaling	0.16 (0.37) N/A	0.04 (0.21) -0.11	0.02 (0.15) -0.14
<b>Subject-Assessed Tolerance</b>			
Burning/Stinging	0.00 (0.00) N/A	0.02 (0.15) 0.02	0.00 (0.00) 0.00
Itching	0.00 (0.00) N/A	0.04 (0.21) 0.04	0.00 (0.00) 0.00
Tightness / Dry feeling	0.07 (0.25) N/A	0.04 (0.21) -0.02	0.02 (0.15) -0.05

## Key Findings

- There were no statistically significant or clinically meaningful increases in irritation observed by either the Investigator or subjects.
- Nearly 98% of subjects showed no erythema or scaling after 4 weeks.
- Based on subject-assessed tolerance, no burning or stinging was present in almost 98% of subjects after 4 weeks.

# Self-Assessment Questionnaire & Conclusions

## Subject Questionnaire

Week 4	% Subject Agreement	
	Full Population	Subset*
Leaves my skin feeling comfortable	86	87
Is gentle to skin	93	90
Skin does not look flaky	91	92

\* Subset of subjects who responded YES to "have you experienced irritation from past topical acne treatments?" – n=38 (84.4%)

## Conclusions

A novel low-level blue and red light therapy was found to be extremely well-tolerated in a mild-to-moderate acne population with self-perceived sensitive skin.

- Objective (erythema and scaling) and subjective (burning/stinging, itching, tightness/dry feeling) tolerance attributes demonstrated no statistically or clinically meaningful increases in irritation.
- 93% of all subjects answered that the mask was gentle to their self-perceived sensitive skin.
- Further, 90% of the patients who had experienced irritation from topical acne treatments in the past agreed that low-level blue and red light therapy was a gentle treatment for their facial skin.

## Key Findings

- The sensitive skin acne subjects agreed strongly that the light therapy treatment was gentle to their skin, left their skin feeling comfortable, and didn't result in flakiness, which is often observed with topical medications.
- 90% of subjects who have experienced irritation from topical acne treatments in the past agreed that the light therapy treatment was gentle to their skin

# Disclosure & References

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