A Single Center, Clinical Study to Determine the Safety and Efficacy of an Eczema Spot Treatment Gel Cream in Providing Eczema Symptoms Relief and Lasting Itch Relief to Affected Skin Area

Prepared for:

Johnson & Johnson Consumer Inc.

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PURPOSE

Eczema is a chronically relapsing skin disease associated with erythema, scaly plaques, and severe pruritus. Signs and symptoms of eczema are associated with a compromised immune system and also a defective skin barrier. Eczema subjects experience frequent cutaneous infections, and *Staphylococcus aureus* is commonly cultured from lesional and non-lesional eczematous skin. Disease states, severity, and treatments are related to microbial dynamics in this common skin disorder. Atopic dermatitis is the most common form of eczema. As a result, clinicians and academic researchers often use the terms “eczema” and “atopic dermatitis” interchangeably. The ADSI score stands for “atopic dermatitis severity index” and is used to grade eczema lesions in clinical studies and was utilized in this study to assess severity of eczema lesions, a specific area of the eczema flare in subjects.

Colloidal Oatmeal has been used for decades to soothe and ameliorate atopic dermatitis. Colloidal Oatmeal is approved by the Food and Drug Administration as a skin protectant drug for over-the-counter use and can “temporarily protect and help relieve minor skin irritation and itching due to eczema”.

GENERAL INFORMATION

Protocol ID:	CCSSKA004706
Protocol Title:	A Single Center, Clinical Study to Determine the Safety and Efficacy of an Eczema Spot Treatment (Gel Cream, F# 13646-156) in Providing Eczema Symptoms Relief and Lasting Itch Relief to Affected Skin Area
Investigational Product (IP):	Gel Cream
Study Start Date:	21 Feb 2022
Study End Date:	09 Mar 2022
Sponsor:	Johnson & Johnson Consumer Inc. 199 Grandview Road Skillman, NJ 08558
Principal Investigator (PI):	Zoe Diana Draelos, M.D.
Study Site:	Dermatology Consulting Services, PLLC 2444 North Main Street High Point, NC, 27262

SUMMARY

This single-center, monadic clinical trial was conducted for Johnson & Johnson Consumer Inc. to evaluate the efficacy (assessed by clinical evaluation of eczema/atopic lesion severity [ADSI scoring] and perceived benefits in itch [VAS scoring]) and tolerability (assessed by clinical grading) of an investigational spot treatment Gel Cream when used on a target site of subjects with mild to moderate eczema.

A total of 37 subjects were enrolled in the study and 35 subjects completed study participation. Of the 37 enrolled subjects, 36 subjects were included in the intent-to-treat (ITT) population, defined as all subjects who used the IP and completed baseline and at least one post-baseline data point; and 37 subjects were included in the Adverse Event (AE) analysis set, defined as all subjects who signed the Informed Consent Document (ICD).

During the course of the study, subjects applied the Gel Cream on the selected target lesion at least twice per day, in the morning and at night, and on the entire face once per day, as directed. Subjects performed the first application of the IP on the target lesion on-site after completion of baseline evaluations.

Subjects were evaluated at Visit 1 (Screening/Baseline, Within 2 Minutes Post-first IP Application, and Remotely at Hours 2 and 4 Post-first IP Application), Visit 2 (Day 3), Visit 3 (Week 1/Day 7), and Visit 4 (Week 2/Day 14). Subjects participated in the following procedures at the indicated time points:

- Atopic Dermatitis Severity Index (ADSI) Assessment
  At Visit 1 (Screening/Baseline), Visit 2 (Day 3), Visit 3 (Week 1/Day 7), and Visit 4 (Week 2/Day 14), the PI evaluated each subject's target lesion for ADSI, which represents the sum of the scores for the following component signs and symptoms: erythema, pruritus, exudation, excoriation, and lichenification.

- Additional Clinical Evaluations
  At Visit 1 (Screening/Baseline), Visit 2 (Day 3), Visit 3 (Week 1/Day 7), and Visit 4 (Week 2/Day 14), the PI evaluated each subject's target lesion for dryness, tactile roughness, and skin tone of lesion compared to normal overall skin tone.

- Additional Tolerance Evaluations
  At Visit 1 (Screening/Baseline), Visit 2 (Day 3), Visit 3 (Week 1/Day 7), and Visit 4 (Week 2/Day 14), the PI evaluated each subject's target lesion and facial skin (evaluated separately) for overall irritation, and asked each subject to rate the severity of burning/stinging sensation on the facial skin.

SUMMARY (continued)

- Itch Assessment
  At Visit 1 (Screening/Baseline, Within 2 Minutes Post-first IP Application, and Remotely at Hours 2 and 4 Post-first IP Application), Visit 2 (Day 3), Visit 3 (Week 1/Day 7), and Visit 4 (Week 2/Day 14), each subject rated the itch severity of the target lesion using a visual analog scale.

- Soothing Assessment
  At Visit 1 (Within 2 minutes Post-first IP Application), subjects rated their level of agreement to how the IP soothed/calmed the eczema test site area (target lesion).

  At Visit 1 (Remotely at Hours 2 and 4 Post-first IP Application), Visit 2 (Day 3), Visit 3 (Week 1/Day 7), and Visit 4 (Week 2/Day 14), subjects rated their level of agreement to how soothed/calmed the eczema test site area (target lesion) felt.

- Cooling Assessment
  At Visit 1 (Within 2 Minutes Post-first IP Application and Remotely at Hour 2 Post-first IP Application), subjects rated their level of agreement to how the IP provided a cooling sensation to the target lesion.

- Digital Photographs
  At Visit 1 (Screening/Baseline), Visit 2 (Day 3), Visit 3 (Week 1/Day 7), and Visit 4 (Week 2/Day 14), a trained photographer took close-up images of each subject's target lesion, with an appropriately draped background, using the Canfield D90 digital SLR camera under visible light.

  After study completion, raw images were provided to the Sponsor.

- Transepidermal Water Loss (TEWL) Measurements
  At Visit 1 (Screening/Baseline), Visit 2 (Day 3), Visit 3 (Week 1/Day 7), and Visit 4 (Week 2/Day 14), two (2) measurements were taken from each subject's target lesion using the RG-1 Evaporimeter (cyberDERM) equipped with DermaLab (Cortex Technologies) probes in conjunction with a computer to measure the transepidermal water loss (TEWL).

- Skin Hydration Measurements
  At Visit 1 (Screening/Baseline), Visit 2 (Day 3), Visit 3 (Week 1/Day 7), and Visit 4 (Week 2/Day 14), three (3) measurements were taken from each subject's target lesion using a DermaLab pin probe attached to a Cortex Technologies computer platform to measure the skin hydration.

- Skin pH Measurements
  At Visit 1 (Screening/Baseline), Visit 2 (Day 3), Visit 3 (Week 1/Day 7), and Visit 4 (Week 2/Day 14), one (1) measurement was taken from each subject's target lesion using a DermaLab pH probe attached to a Cortex Technologies computer platform to measure the skin pH.

- Microbiome Swabs
  At Visit 1 (Screening/Baseline), Visit 2 (Day 3), Visit 3 (Week 1/Day 7), and Visit 4 (Week 2/Day 14), surface skin microbiome was collected from each subject's target lesion.

  After study completion, collected swabs were sent to a Sponsor-appointed external laboratory (CosmosID Inc., Germantown, MD) for DNA extraction and analysis to determine the effect of the IP on the skin microflora. The results from the microbiome analysis will be included in a supplemental report.

SUMMARY (continued)

- Subject Self-assessment: Itch Quality of Life Questionnaire
  At Visit 1 (Screening/Baseline), Visit 2 (Day 3), Visit 3 (Week 1/Day 7), and Visit 4 (Week 2/Day 14), subjects completed a Sponsor-provided itch-specific Quality of Life (QOL) questionnaire.

- Subject Self-assessment: Dermatology Life Quality Index (DLQI)
  At Visit 1 (Screening/Baseline), Visit 3 (Week 1/Day 7), and Visit 4 (Week 2/Day 14), subjects completed a validated self-reported questionnaire designed to measure the health-related quality of life of adult patients suffering from a skin disease

- Subject Self-assessment: Final Assessment Questionnaire
  At Visit 4 (Week 2/Day 14), subjects completed a Sponsor-provided self-assessment questionnaire regarding product performance.

Overall Conclusions

Overall results from this single-center, monadic clinical trial indicate that the Sponsor's investigational spot treatment Gel Cream was effective in improving eczema on the target lesions and improving skin barrier properties and skin hydration, when used over the course of 2 weeks by subjects with mild to moderate eczema, under the conditions of this test. The Gel Cream was also effective in providing instant cooling sensation that lasted over 2 hours after a single application; and a soothing/calming sensation throughout the study (instantly and through 4 hours after a single application, and after 3 through 14 days of use). Subjects perceived itch relief upon product used and throughout the duration on the study (instantly and through 4 hours after a single application, and after 3 through 14 days of use). Additionally, a significant improvement in the mean global DLQI was noted after 2 weeks of using the Gel Cream on the target lesion. The Gel Cream was well tolerated as perceived the PI and the subjects.

Results of the clinical evaluation showed a statistically significant ($P \leq 0.05$) decrease (improvement) in scores for the atopic dermatitis severity index (ADSI) (cumulative score from the individual parameters); erythema, pruritus, and lichenification (individual parameters from ADSI assessment); and dryness, tactile roughness, and skin tone of lesion compared to normal overall skin tone at Visit 2 (Day 3), Visit 3 (Week 1/Day 7), and Visit 4 (Week 2/Day 14); and for exudation (individual parameter from ADSI assessment) at Visit 3 (Week 1/Day 7), when compared with Baseline. There was no statistically significant ($P > 0.05$) change in scores for excoriation (individual parameter from ADSI assessment) at any evaluated post-baseline time point when compared with Baseline.

Results of the bioinstrumentation measurements showed a statistically significant ($P \leq 0.05$) decrease in TEWL values (improvement in skin barrier properties) at Visit 2 (Day 3) and Visit 4 (Week 2/Day 14); and a statistically significant ($P \leq 0.05$) increase (improvement) in skin hydration values at Visit 2 (Day 3), Visit 3 (Week 1/Day 7), and Visit 4 (Week 2/Day 14), when compared with Baseline. There was no statistically significant ($P > 0.05$) change in skin pH values at any evaluated post-baseline time point when compared with Baseline.

Results of the subjective assessments showed a statistically significant ($P \leq 0.05$) decrease (improvements) in itch assessment at Visit 1 (Within 2 minutes Post-first IP Application and at Hours 2 and 4 Post-first IP Application), Visit 2 (Day 3), Visit 3 (Week 1/Day 7), and Visit 4 (Week 2/Day 14), when compared with Baseline. Additionally, a statistically significantly ($P \leq 0.05$) greater proportion of subjects responded favorably that the IP soothed/calmed their eczema test site area (target lesion) at Visit 1 (Within 2 minutes Post-first IP Application), and that the target lesion felt soothed/calmed at Visit 1 (Hours 2 and 4 Post-first IP Application), Visit 2 (Day 3), Visit 3 (Week 1/Day 7), and Visit 4 (Week 2/Day 14); and that the IP provided a cooling sensation to the target lesion at Visit 1 (Within 2 minutes Post-first IP Application and at Hour 2 Post-first IP Application).

Results of the tolerance evaluations showed a statistically significant ($P \leq 0.05$) decrease (improvement) in scores for overall irritation of the target lesion and facial skin, as evaluated separately by the PI, and in scores for burning/stinging of the target lesion and facial skin, as evaluated together by the subjects, at Visit 2 (Day 3), Visit 3 (Week 1/Day 7), and Visit 4 (Week 2/Day 14), when compared with Baseline.

SUMMARY (continued)

Overall Conclusions (continued)
Results of the Itch Quality of Life questionnaire showed that subjects indicated a statistically significant ($P \leq 0.05$) improvement in their perceptions of the listed statements at the specified post-baseline time points when compared with Baseline:

- For Frequency statements:
    - At Visit 4 (Week 2/Day 14): My itchy skin condition interferes with my sex life; My personality has changed because of my itchy skin condition; My self-esteem has changed because of my itchy skin condition
    - At Visit 3 (Week 1/Day 7) and Visit 4 (Week 2/Day 14): My itchy skin condition limits the types of foods I can eat; I worry about what other people think about me because of my itchy skin condition
    - At Visit 2 (Day 3), Visit 3 (Week 1/Day 7), and Visit 4 (Week 2/Day 14): My itchy skin condition bleeds; My skin hurts because of my itchy skin condition; My itchy skin condition burns or stings; I get scars from my itchy skin condition; I need to scratch my itchy skin condition; Temperature/seasonal changes aggravate my itchy skin condition; I spend a lot of money treating my itchy skin condition; My itchy skin condition makes it hard to work or do what I enjoy; My itchy skin condition affects my interaction with others; I tend to stay home because I don't want to scratch in public; My itchy skin condition affects how I sleep at night; My itchy skin often makes it difficult to concentrate; My itchy skin condition limits the types of clothes I can wear; My itchy skin condition forces me to buy special soaps, detergents, and lotions; I am frustrated by my itchy skin condition; I am embarrassed by my itchy skin condition; My itchy skin condition drives me crazy/nuts; My itchy skin condition makes me feel angry or irritable; My itchy skin condition makes me feel depressed or sad; I worry that the itching will last forever; I feel self-conscious because of my itchy skin condition
- For Bother statements:
    - At Visit 4 (Week 2/Day 14): My itchy skin condition interferes with my sex life; My itchy skin condition makes me feel depressed or sad
    - At Visit 3 (Week 1/Day 7) and Visit 4 (Week 2/day 14): My skin hurts because of my itchy skin condition; My itchy skin condition affects how I sleep at night; My itchy skin often makes it difficult to concentrate; My itchy skin condition limits the types of foods I can eat; My itchy skin condition limits the types of clothes I can wear; My itchy skin condition forces me to buy special soaps, detergents, and lotions; My itchy skin condition drives me crazy/nuts; My itchy skin condition makes me feel angry or irritable; I worry about what other people think about me because of my itchy skin condition; My self-esteem has changed because of my itchy skin condition
    - At visit 2 (Day 3), Visit 3 (Week 1/Day 7), and Visit 4 (Week 2/Day 14): My itchy skin condition bleeds; My itchy skin condition burns or stings; I get scars from my itchy skin condition; I need to scratch my itchy skin condition; Temperature/seasonal changes aggravate my itchy skin condition; I spend a lot of money treating my itchy skin condition; My itchy skin condition makes it hard to work or do what I enjoy; My itchy skin condition affects my interaction with others; I am frustrated by my itchy skin condition; I am embarrassed by my itchy skin condition; I worry that the itching will last forever; I feel self-conscious because of my itchy skin condition

SUMMARY (continued)

Overall Conclusions (continued)
Results of the Dermatology Life Quality Index (DLQI) showed a statistically significant ($P \leq 0.05$) decrease (improvement) in subject response values for Questions 1-8 and 10 individually, symptoms and feelings subscale (questions 1 and 2), daily activities subscale (questions 3 and 4), leisure subscale (questions 5 and 6), work and school subscale (question 7), personal relationships subscale (questions 8 and 9), and treatment subscale (question 10), at Visit 3 (Week 1/Day 7) and Visit 4(Week 2/Day 14) when compared with Baseline. The results of the DLQI showed a statistically significant ($P \leq 0.05$) decrease (improvement) in the total DLQI scores at Visit 3 (Week 1/Day 7) and Visit 4 (Week 2/Day 14) when compared with Baseline. A significant improvement in the mean global DLQI was noted after 2 weeks of using the Gel Cream on the target lesion. At Baseline, subjects' mean global DLQI score (8.37) indicated the eczema had a moderate effect on the subjects' lives, and after 2 weeks of using the Gel Cream on the target lesion, the subjects' mean global DLQI score (2.34) indicated that the eczema had a small effect on the subjects' lives. Additionally, the mean change from Baseline in the total DLQI scores showed a Minimal Clinically Important Difference (MCID)* at Visit 3 (Week 1/Day 7) and Visit 4 (Week 2/Day 14).

*Note: A change in DLQI score of at least four points is considered clinically important.[2]

Results of the Final Assessment questionnaire completed at Visit 4 (Week 2/Day 14) showed that a statistically significantly ($P \leq 0.05$) greater proportion of subjects selected favorable responses (strongly agree or agree) to all inquiries (as listed below) regarding application experience of the IP and perceived improvements in the look and feel or target lesion, indicating positive subject perceptions of the IP:

- This Gel Cream provides instant soothing relief for my itchy dry skin area
- This Gel Cream instantly cools and soothes my itchy dry skin area
- This Gel Cream provides soothing/calming itch relief to my itchy dry skin area
- This Gel Cream provides lasting itch relief to my itchy dry skin area
- This Gel Cream soothes and relieves my itch
- This Gel Cream provides cooling relief to itchy dry skin area
- This Gel Cream left my area of irritated itchy dry skin feeling less bothersome
- This Gel Cream left my itchy dry skin area looking healthier
- This Gel Cream left my itchy dry skin area feeling moisturized
- My itchy dry skin area has a more even skin tone
- This Gel Cream allows me to be better prepared to manage my itchy dry skin flare ups
- This Gel Cream absorbed quickly
- This Gel Cream was non greasy
- This Gel Cream spread easily

Adverse Events (AE)
Study Related Non-serious AEs for 2 subjects:

- Moderate irritant contact dermatitis on the face and eyes (probable relationship)
- Mild facial acne (possible relationship)

No serious AE (SAEs) or other significant AEs were reported/observed in this study.

REFERENCES

1. Rajka G and Langeland T. Grading of the severity of atopic dermatitis. *Acta Derm Venereol (Stockh)*. 1989;144:13-14.
2. Finlay, A. Y. and Khan, G. K. 1994. Dermatology Life Quality Index (DLQI)--a simple practical measure for routine clinical use. Clinical and Experimental Dermatology 19 (3), pp.210-216. (10.1111/j.1365-2230.1994.tb01167.x)

REPORT APPROVAL

Report approved by:

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