



The Sudocrem Real World Evidence (SURE) Study

**A novel design for real world data capture
using social media**

*Dr Martin Goldman, * Chief Medical Officer, Iatros Consulting, London, UK
Dr Imran Lodhi, Medical Director, Allergan Ltd, Marlow, UK*

Rationale

Sudocrem Antiseptic Healing Cream (SAHC) is a licensed water-in-oil emulsion with several indications including the treatment of nappy rash. It contains the following:¹

Ingredient	Properties
Zinc oxide	Soothing and protective astringent
Benzyl alcohol	Local anaesthetic with disinfectant properties
Benzyl benzoate	Acaricide, pediculicide, insect repellent and pharmaceutical solubilising agent
Benzyl cinnamate	The other principal ester of Peru Balsam BPC 1973. Synthesised from benzyl alcohol and cinnamic acid which has antibacterial and antifungal properties. Peru Balsam is categorised as having mild antiseptic action due to the presence of cinnamic acid and its derivatives
Lanolin	Hypollergenic grade emollient with similar sebaceous properties to human skin

The barrier properties of SAHC are related to its excipients of waxes and paraffin oil. While the efficacy of Sudocrem was established in two legacy studies,^{2,3} these did not specifically address the healing of infantile nappy rash.

Social media represents a novel approach to real-world data capture, with quick recruitment and minimal cost. This methodology may be particularly important to older products or nursing interventions that are generally accepted as effective, but where it might be challenging to initiate a conventional clinical trial and/or where there are no standard evidence-based treatments.

A retrospective non-interventional real-world data study was conducted using social media to investigate the experience of users of SAHC for treating an episode of infantile nappy rash or infantile incontinence dermatitis.

Methods

- Users were recruited through Sudocrem social media channels (~45%) or through an email to 100,000 parents/carers who were members of the Bounty Parenting Club digital community (~55%).
- Inclusion criteria were the child being ≤ 3 years old and use of SAHC to treat the reported episode of nappy rash.
- Data was collected using a bespoke Internet platform 'SurveyGizmo' application configured for use on home computers, tablets and smart-phones. Cohort size was set from 200 respondents (minimal credible number) up to a maximum of about 2000 (considered to be representative of the general population). Participants confirmed the use of SAHC to treat an episode of nappy rash in a child, and the questionnaire asked for details of how it was used and the outcome experienced.
- A pilot study preceded the main study to confirm method viability and resolve any ambiguity of the questions. These data were not included in the results, but the sequencing of questions was modified to eliminate non-logical progression through the questionnaire.

Participants

- A total of 2159 respondents were recruited into the study within 9 days. The results of 1818 respondents who had used the product within the previous 6 months (74% within the past 4 weeks) were reported to reduce recall bias.
- The mean age of the children was 17.9 months (SD 9.4 months; range 0–36 months).
- The majority of children (94.8%) were reported to have slight to moderate nappy rash (representing 5 points on a 7 point Likert scale).

Results

Measures of inflammation

- A rapid reduction was recorded in four observed signs of inflammation. The fifth element of inflammation, loss of skin function, could not be measured in this study.

Speed of response and healing

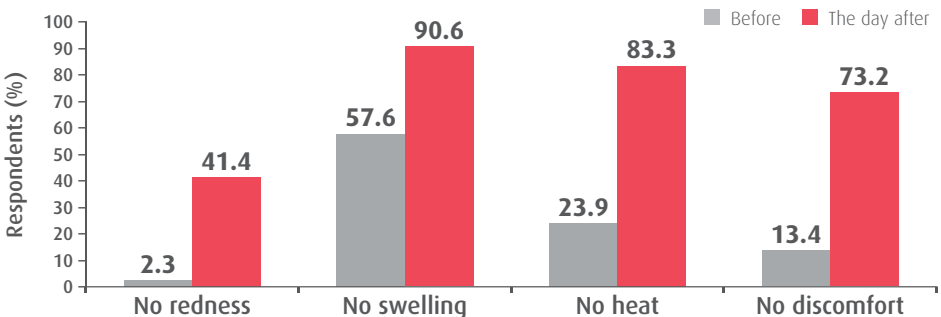
- Over 50% of respondents saw an improvement in nappy rash on the same day that treatment was started, and within 3 days, 94.5% of respondents had reported an improvement in nappy rash.

- The respondents were asked at what point they thought the nappy rash had completely healed. Of 1804 subjects who answered the question, 72.5% indicated that the nappy rash had completely healed within 3 days of starting treatment and by the 5th day, 94.7% said that the nappy rash had completely healed.

Impact of nappy rash on family life

- 71% of 1793 carers said that an episode of nappy rash had either no or minimal impact on family life, but 29% reported a noticeable impact.

The SURE study: results – Inflammation: *Four characteristics evaluated¹*



1. Based on 1816 responses representing those who had used SAHC in the previous 6 months 2. Discomfort was used as a surrogate parameter for 'pain' 3. Before indicates before applying SAHC and the day after indicates the day after the first application of SAHC

References: 1. Sudocrem Antiseptic Healing Cream. Summary of Product Characteristics. Forest Laboratories Limited, 2013. 2. Mitchell JK, *et al.* The Treatment of Paediatric Rashes. *Clinical Trials Journal* (London) 1982, 19, 1, 17–19. 3. Anthony D, *et al.* A clinical study of Sudocrem in the management of dermatitis due to the physical stress of incontinence in a geriatric population. *Journal of Advanced Nursing*. 1987; 12:599–603.

Conclusions

- The study supports the use and validity of social media as a means of real-world data capture.
- The results of this real-world retrospective study show that SAHC is associated with rapid skin healing and a reduction in perceived signs of inflammation.
- There was no statistically significant difference in findings between the overall cohort of 2159 participants and the results reported in the cohort of 1818 participants.
- The SURE study has the expected limitations of a retrospective, patient (carer)-reported outcome study, including confounding factors (other products being used, co-morbidities, types of nappy used, frequency of changing etc). However, these data from over 2000 carers are likely to be more representative of the real-life scenario of nappy rash treatment outcomes than the more limited data from a clinical trial.

Sudocrem[®]