Himalaya®
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90+ YEARS OF TRUST

CLINICAL STUDY REPORT

soothing calamine baby lotion

Effectively heals rashes

Calms and soothes baby's skin

Promoted exclusively to DOCTORS

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Clinical Credentials

soothing calamine baby lotion

HRIPT (Human Repeat Insult Patch Test)*

Number of subjects: 201

Age group: 18 years-65 years

Clinical study outcome: **soothing calamine baby lotion** emerged as hypoallergenic in the test population with no indicative allergenic response in the challenge phase. It emerged to be mild and gentle on the skin of the test population.

In-Use Clinical Efficacy Study

Number of subjects: 100

Age group: 0 years-5 years

Clinical study outcome: At the time of completion of the study, an average reduction was found in:

- **Prickly Heat: 83.87%**
- **Swelling: 64.50%**
- **Pain: 77.77%**

Soothing calamine baby lotion can be used twice daily and helps in reduction of prickly heat, urticaria, and insect bite lesions and associated symptoms.

*** Study conducted as per:**

- BIS 4011:2018 guideline
- CDSCO (Central Drug Standard Control Organization) guideline
- ICH-GCP (Good Clinical Practice) guideline
- Principles stated in the "Declaration of Helsinki"

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HRIPT (Human Repeat Insult Patch Test):

Evaluation of skin sensitization potential of an investigational product by Human Repeat Insult Patch Test (HRIPT). (As per BIS guideline 4011:2018)

The objective of this study was to determine the sensitization potential of each product and to determine the cumulative irritation potential of the test product by 9 occlusive applications under occlusion. This is single-center, evaluator-blinded, sensitization study in healthy adult human subjects (18 to 65 years of age) using repeat insult patch testing conducted at independent CRO in the year 2020. Qualified subjects finished all three phases of the study (i.e., induction, rest, and challenge).

Each test material was applied three (3) times a week for a total of nine (9) applications followed by a two (2) weeks rest period {minimum of twelve (12) days and a maximum of twenty-four (24) days}. After the rest period, a 48-hour challenge application of each material was made.

The Study was initiated after the Ethics Committee's approval; study protocol and other study documents were submitted to Independent Ethics Committee and the study was approved on 26th May, 2020. Subjects were enrolled in the study after voluntarily signing the informed consent form. 201 subjects completed the study. All subjects received the test product along with Negative Control as per the guidelines.

Occluded patches were used in the study (i.e., Finn Chambers measuring about 1 cm diameter). 1 cm diameter filter paper was placed on the Finn Chamber Disc. Then, the test product was applied on the filter paper. Only the area beneath the patch was considered for the irritation observation and any sign of irritation due to the tape was not considered as patch irritation. No tape irritation was observed in this study.

Investigational Product: **soothing calamine baby lotion**

Number of subjects: 201

Number of Patches: Each test material was to be applied three (3) times a week for a total of nine (9) applications followed by a two (2) weeks rest period {minimum of twelve (12) days and a maximum of twenty-four (24) days}. After the rest period, a 48-hour challenge application of each material was to be made.

Study Methodology:

The study was conducted over a period of approximately 6 weeks for each subject to confirm that the test substances would not produce evidence of delayed contact sensitization following external contact with the skin by means of a repeated patch application procedure. The study was conducted on male and female subjects, 18 to 65 years of age. This study was comprised of 3 phases as follows:

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Induction Phase: A volume of 40 µl of the test product (diluted or pure, according to the type of product) was applied after loading on the occlusive chambers under occlusion for three (3) weeks at the frequency of three (3) applications a week. A negative control with 0.9% normal saline was applied along with the test product on every patch application visit. The product was applied to the upper back of subjects after ensuring that the skin was free from any active diseases. The other site where no patch was applied served as a non-treated control. The patch applied, was required to stay in place for twenty-four (24) hours and was reapplied each time on the same site after evaluation by the dermatologist. The days of patch application were on visits 2, 3, 4, 5, 6, 7, 8, 9, and 10. The evaluation was done 24 hours post-patch removal, and the fresh patch was applied immediately after evaluation.

Rest Phase: During the 2 weeks of rest phase, no patch was applied. The previous reaction seen in test sites (product sites) should have completely subsided in the rest phase. The rest phase could be of minimum twelve (12) days, and a maximum of twenty-four (24) days.

Challenge Phase: During the challenge phase, the test product was reapplied in a patch following the same procedure at a new contralateral naive test site, as used in the Induction Phase. The applied patch was taken off twenty-four (24) hours after application and a series of clinical readings were carried out at 24 hours, 48 hours, and 72 hours.

Re-challenge Phase (only for those products that show a positive response in the Challenge Phase): Subjects, indicative of allergic dermatitis, as per the reactions observed in the challenge phase were to be patched with the indicated product on the original site and another site on the back to affirm the nature of the reaction. As none of the subjects showed an indicative allergenic response, the re-challenge phase (confirmatory patch application) was not done.

Executive Result:

- The test product emerged as hypoallergenic in the test population with no indicative allergenic response in the challenge phase.
- The test product emerged to be mild and gentle on the skin of the test population.
- Since the test product in the formulation emerged as hypoallergenic, it can be inferred that it will not show any allergenic reactions in majority of the population.

Individual response may vary due to preexisting sensitization/allergy with any of the ingredients.

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In-Use Clinical Efficacy Study:

Once the safety study is completed, the Himalaya baby product will be tested on the target population. This kind of study is called in-use study or claim substantiation study. This study is conducted to support all the claims on the pack for that particular product.

The Study was conducted at Kids Care clinic under the supervision of Dr. Chandrakanth Mahale in the year 2017. It was a phase II study and Ethics Committee's approval was not mandatory. Subjects were enrolled in the study after voluntarily signing the informed consent form by their mothers/caretakers. All enrolled subjects underwent all assessments as per the protocol, and 31 subjects completed the study.

Name of Product: **soothing calamine baby lotion**

Title of Study: A clinical study to evaluate the efficacy of **soothing calamine baby lotion** in children with prickly heat, urticaria, and insect bites

Study Center: Kids Care clinic – Vijayanagar, #23rd, 1st Floor, 3rd Main, Chandra Layout Main Road, Vijaynagar. Landmark: Near Maruthi Petrol Bunk, Bengaluru-560 040

Objectives:

Primary objective: Evaluate reduction in prickly heat, urticaria, insect bites, and symptomatic relief in symptoms.

Secondary objective: Evaluate the safety of **soothing calamine baby lotion**

Number of subjects: 31 subjects

Inclusion Criteria:

- Children with the clinical diagnosis of miliaria (prickly heat), urticaria, and insect bites
- Infants born at term with a birth weight of more than 2500 g and in the age group of 0-5 years
- Infants with appropriate weight gain, length, and head circumference
- Infants with normal psychomotor development
- Infants whose parents are willing to give informed written consent

Exclusion Criteria:

- Babies suffering from some systemic or topical disease
- Babies with any congenital abnormalities
- Babies who were under some regular medication except for vitamin supplements.
- Babies whose parents were not willing to give informed written consent

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Efficacy and Safety Evaluation: IP which is a lotion with the primary efficacy for prickly heat and urticarial and insect bite lesions was evaluated for 14 days among 31 subjects. At the time of completion of the study the average reduction in prickly heat was found to be 83.87%, swelling 64.50% and pain 77.77%. No adverse events were reported during the study.

Conclusion: The current IP, which is a lotion, can be used twice daily and helps in the reduction of prickly heat, urticarial and insect bite lesions, and associated symptoms.

soothing calamine baby lotion **Himalaya**

Effectively heals rashes • Calms and soothes baby's skin

Helps soothe and protect skin from rashes and irritation

Helps relieve itching

Helps moisturize skin

Helps soothe rashes

- Anti-inflammatory property helps soothe red and inflamed skin.
- Antimicrobial property helps protect against infection.
- Antipruritic and cooling properties help relieve itching.
- Soothing property helps relieve pain due to inflammation.
- Emollient property moisturizes dry and itchy skin.

Directions for use

- Apply gently to the affected area
- Recommended to apply twice a day for best results

Available in 100 ml

FREE FROM
Parabens
Mineral Oil
Phthalates

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Helps moisturize skin

Helps soothe rashes

Indications

For the symptomatic management of skin rashes, itching, and irritation or inflammation due to:

- Hives (urticaria)
- Prickly heat/Miliaria
- Insect bite
- Chicken pox
- Allergic reaction

FREE FROM
Parabens
Mineral Oil
Phthalates

For the use of only a registered medical practitioner, or a hospital, or a laboratory.

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