# Efficacy assessment during a controlled clinical in-use study of a topically applied cosmetic product in the treatment of plantar hyperhidrosis

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## Introduction

Hyperhidrosis is a disorder of excessive sweating beyond what is expected for thermoregulatory needs and environmental conditions.[1,2] Hyperhidrosis may be primary or secondary to medications or general medical conditions.[2]

Primary hyperhidrosis is idiopathic; it results from over-activity of the sympathetic nerves and involves a limited body area, most often theaxillae, palms, soles, or craniofacial regions.[1] Secondary hyperhidrosis results from an underlying medical condition or use of prescription medications and implicates the entire body.[1]

Hyperhidrosis can range in severity from mild dampness to severe dripping and can result in substantial impairment in quality of life. This includes limitations in work and social relationships, physical and leisure activities, and impairments in emotional and mental health. The negative impact caused by excessive sweating has been reported to be like, if not greater than, the negative impact caused by conditions, such aspsoriasis and other chronic diseases.[1]

The treatment of hyperhidrosis is clinically dynamic due to the variety of treatment options available. Therapy options may be broadly classified as nonsurgical and surgical. Nonsurgical options include medical treatments (topical and systemic medications) and procedural treatments (iontophoresis and botulinum toxin injection).[2] First-line nonsurgical therapy involves topical agents suchas aluminum chloride.[3] Aluminum salts have been used for more than 80 years and are inexpensive, easily available, and nontoxic, so they remain the common active ingredient of most preparations.[4] In general first-line treatment of all primary hyperhidrosis, regardless of severity, is topical 20% aluminum chloride.[5] However, today there are a lot of natural actives with proven effectiveness against hyperhidrosis.

## Aim

The primary aim of the study is to assess the instant and long-term efficacy of Lamisil Sweat Absorbing Foot Cream.

## Study Specifications

### METHODOLOGICAL APPROACH

This controlled clinical in-use study was performed on a panel of healthy human subjects, defined as non-interventional clinical research, according to the ethical principles for medical research (Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly Helsinki, Finland, June 1964, and successive amendments) and with all relevant national guidelines.

There was no placebo or positive control group defined. The subject was used as its own control because hyperhidrosis can vary from person to person.

The application of the product will be done in a controlled way by the subjects which needed to follow the instructions of use thoroughly. As directed in the instructions of use, the subjects needed to apply the product for three days to have a therapeutic build-up in the respective treatment area. After that initial treatment period, they had to follow up their sweating behavior for the remaining 8 days.

The study was performed to assess the instant and long-term efficacy of Lamisil Sweat Absorbing Foot Cream, using a numerical rating scale (NRS). This is a validated tool used for the self-reporting assessment of skin conditions.[6] The NRS used in this study is based on the visual and photonumeric scale used for the quantification of hyperhidrosis described by Lyra et al.[7] One point was added to the 4-point photonumeric rating scale described by Lyra et al.[7] because Lamisil Sweat Absorbing Foot Cream will completely stop sweating in some volunteers. So, the defined NRS for this study is a 5-point NRS ranging from 1 = no sweat, 2 = little sweating, 3 = wet sweating, 4 = soaked and dripping sweating, and 5 = soaked and very dripping sweating.

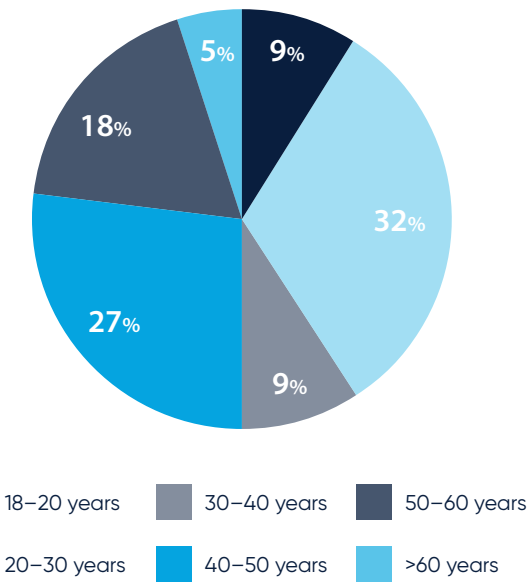


**FIGURE 1: Age Demographics**

In addition to this primary endpoint, product parameters (scent, feeling and spreadability), and a tolerance parameter are being rated by the subjects as well. To assess the product parameters, a numeric 5-point scale was used where 1 = very bad and 5 = very good. The tolerance parameter is assessed by the yes-no question whether the volunteers suffered from irritated skin during or after use of Lamisil Sweat Absorbing Foot Cream.

For this study, 20 volunteers are sufficient to obtain statistical significance of the proposed endpoints. An estimated 10% drop-out was included resulting in a total of 22 volunteers. None of the volunteers dropped out during the study.

Subjects were enrolled if they were ≥18 years, male or female, Caucasian, presenting with plantar excessive sweating, and otherwise healthy. Participants could withdraw at any time, and investigators could withdraw subjects due to adverse events, protocol deviations, or other clinical reasons. Data collected prior to withdrawal were retained.

## Results

### DESCRIPTIVE STATISTICS

A total of 22 subjects were included. Most participants were aged 20–30 and 40–50 years (Figure 1), aligning with age groups commonly affected by primary hyperhidrosis, namely 25-64 years.[1]

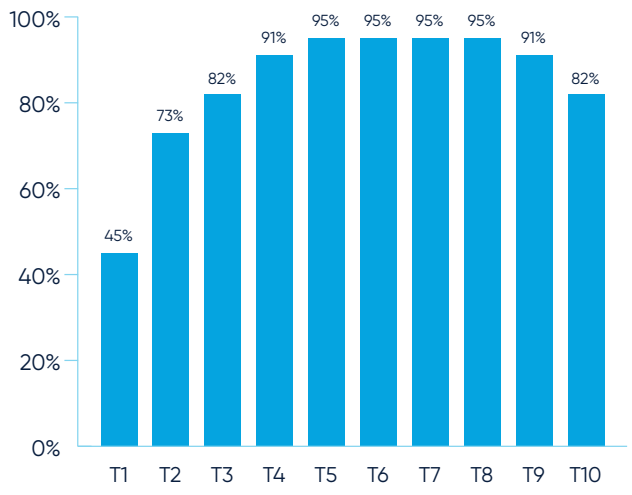


**FIGURE 2: Efficacy in time**

### EFFICACY

The subjects received one tube, containing the formulation of Lamisil Sweat Absorbing Foot Cream. 45% of the subjects reported an immediate hyperhidrosis reduction after only one application. After the initial treatment period, 91% of the subjects indicated that their plantar hyperhidrosis was reduced, which lasted up to 10 days for 82% of the subjects subjects (Figure 2).

### PRODUCT PARAMETERS

Subjects also evaluated scent, feel, and spreadability. Scent, an important factor for patient compliance, received an average score of 4.0/5, indicating good acceptability. The feeling after application and spreadability scored 4.0 and 4.4/5, respectively, suggesting very good performance. No significant irritation, such as burning or prickling, was reported. Overall, the product shows good tolerance and a favorable sensitization profile.

## Conclusion

The controlled clinical in-use study aimed to determine whether a new cosmetic product Lamisil Sweat Absorbing Foot Cream provided an instant and long-term efficacy in reducing excessive sweating. The results of this study showed that the formula of Lamisil Sweat Absorbing Foot Cream had an instant efficacy after one application, which was reinforced after the initial treatment period and lasted up to 10 days. In addition, the product parameters (feeling, scent and spreadability) and tolerance profile were indicated as good for Lamisil Sweat Absorbing Foot Cream.

## References

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