

Assessment of the efficacy, tolerance, and regenerative properties of Cicaplast Baume B5+ Balm — results of an observational study

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ABSTRACT

Background: The skin, as the body's largest organ, is prone to various forms of damage, ranging from minor abrasions to complex dermatological conditions. Effective treatments are essential to promote skin regeneration while minimizing infection and scarring risks. This study evaluates the regenerative properties of Cicaplast Baume B5+ Balm (La Roche-Posay), a topical treatment with 5% panthenol (vitamin B₅) and madecassoside, across a range of skin conditions.

Material and methods: A total of 364 participants, who underwent recent dermatological procedures or experienced conditions like contact dermatitis or actinic keratosis, were recruited. Participants applied the balm twice daily for 14 days, and data on wound healing, symptom reduction, and patient satisfaction were collected *via* questionnaires.

Results: The results demonstrated significant improvement in skin healing in 84% of patients, with reductions in erythema (84.5%), desquamation (69.5%), and fissures (54%). Both patients and doctors reported high satisfaction, with over 96% rating the balm's effectiveness as "good" or "excellent". Almost all patients (98.4%) were satisfied with its soothing effects and ease of application. While the study confirms the balm's efficacy in promoting skin recovery, the lack of a control group and the short follow-up period are notable limitations.

Conclusions: Overall, Cicaplast Baume B5+ Balm proves to be an effective treatment for enhancing skin regeneration and alleviating discomfort across various dermatological conditions.

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INTRODUCTION

The skin, as the largest organ of the human body, plays a crucial role in protecting against external aggressors, regulating body temperature, and maintaining homeostasis. Despite its robust nature, the skin is frequently subject to various forms of damage, ranging from minor abrasions to more severe dermatological conditions such as eczema, various forms of dermatitis, and skin irritation/superficial wounds after laser treatment and other dermatological procedures. Effective management of these conditions necessitates the use of therapeutic agents that can promote rapid and comprehensive skin regeneration while minimizing the risk of infection and scarring.

Cicaplast Baume B5+ Balm (La Roche-Posay, Warsaw) has emerged as a promising topical treatment designed to enhance skin repair and alleviate discomfort associated with various dermatological conditions. This formulation incorporates a 5% concentration of panthenol (vitamin B₅), which is renowned for its hydrating and anti-inflammatory properties; alongside other active ingredients *e.g.* madecassoside, the major triterpene from *Centella asiatica* that collectively support the skin's natural healing processes [1–3].

This paper aims to investigate the regenerative properties of Cicaplast Baume B5+ Balm across a spectrum of dermatological conditions. By evaluating its efficacy in clinical settings, this study seeks to provide a comprehensive

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Table 1. Indications for use of Cicaplast Baume B5+ Balm

<p>1. Care of superficial wounds, contact dermatitis, and as an adjunctive therapy for the treatment of solar keratosis specified as:</p> <ul style="list-style-type: none"> • nonspecific dermatitis with irritation and cracking • dry eczema • irritation due to abrasion • diaper dermatitis (without exudative lesions) • cheilitis and/or angular cheilosis (inflammation of the corners of the mouth) • inflammation of the vulva or balanoposthitis • superficial burns • superficial skin fissures • adjuvant therapy for the treatment of solar keratosis (imiquimod, 5-fluorouracil) • other
<p>2. Post-treatment condition specified as:</p> <p>a) non-invasive/no dermabrasion:</p> <ul style="list-style-type: none"> • superficial peels • photodynamic therapy • cryotherapy • laser treatment (pulsed dye laser, fractional CO₂ laser, alexandrite laser, and IPL) <p>b) invasive/dermabrasion: (Q-switched lasers, ablative CO₂ laser, electrocoagulation, curettage, microneedling)</p>
<p>3. Other</p>

IPL — intense pulse light

understanding of its potential benefits, thereby offering insights into its role in dermatological therapy. The findings will contribute to the growing body of evidence supporting the use of targeted balms in skin repair and underscore the importance of innovative formulations in dermatology.

MATERIAL AND METHODS

Study design and participants

This study was conducted between January and March 2023 and recruited a total of 364 individuals. The participant cohort comprised 238 (64.8%) female and 128 (35.2%) male patients, with 87 individuals (23.9%) being under the age of 18 (Tab. 1). The inclusion criteria targeted individuals who had undergone recent cosmetic or dermatologic procedures, were diagnosed with various dermatoses *e.g.* contact dermatitis, had superficial skin trauma or were receiving treatment for actinic keratosis (Tab. 1).

Data collection

Data was collected through specifically designed paper questionnaires administered at two key points: the baseline visit, and a follow-up visit after at least 14 days. The questionnaires were crafted to capture detailed information on the wound healing progress, patient satisfaction, and any adverse effects observed during the treatment period.

Patients requiring topical antibiotics, or any other prescribed treatments were excluded from the study to

ensure that the effects observed could be attributed solely to Cicaplast Baume B5+ Balm.

Procedures

During the baseline visit, patients received an initial assessment, and detailed information was recorded regarding their medical history, type of dermatologic condition, and specifics of any recent procedures. Each patient was then provided with Cicaplast Baume B5+ Balm and instructed on its application. Participants were instructed to use Cicaplast Baume B5+ Balm twice daily on the affected area.

The follow-up visit, scheduled 14 days after the baseline visit, involved a comprehensive reassessment of the wound healing progress and overall skin condition. Patients were required to complete the follow-up questionnaires at this visit, ensuring accurate and thorough data collection.

Statistical analysis

The collected data were analyzed to determine the efficacy of Cicaplast Baume B5+ Balm in different dermatological contexts. Statistical methods were employed to compare baseline and follow-up data, with particular attention given to the rate of wound healing, reduction in symptoms associated with dermatoses, and improvement in actinic keratosis lesions. Subgroup analyses were performed to evaluate any differences in outcomes based on age and gender.

The statistical analyses in this observational study were based on determining the empirical distribution of variables, utilizing both tabular descriptions and graphical data presentation methods. All variables in the study were measured on nominal and ordinal scales. To test the hypothesis regarding the effectiveness of Cicaplast Baume B5+ Balm in the treatment of patients requiring regenerative skin care, statistical tests for two dependent samples were performed using the Wilcoxon signed-rank test. This analysis focused on variables measured on an ordinal scale during both the initial and follow-up visits, including the severity of symptoms such as erythema, peeling, pigmentation, cracking, and swelling.

This robust methodology enabled a thorough assessment of Cicaplast Baume B5+ Balm regenerative properties, providing valuable insights into its therapeutic potential in dermatology.

RESULTS

Study population

A total of 364 individuals participated in the study, providing a broad and representative sample for evaluating the regenerative properties of Cicaplast Baume B5+ Balm. The study included 236 women (64.8%) and 128 men (35.2%), with 87 participants (23.9%) being under the age of 18. The majority of participants had skin phototype II, as classified

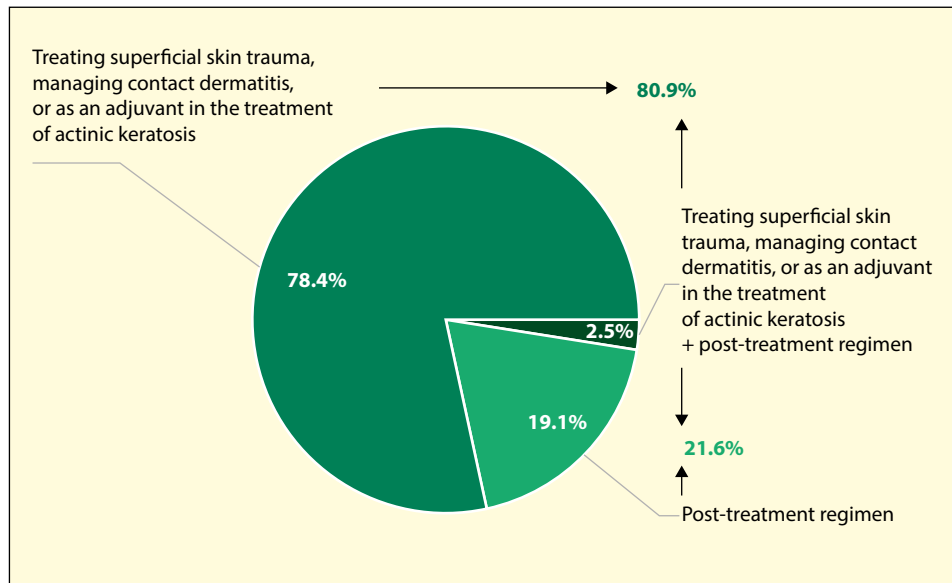


Figure 1. Distribution of indications for Cicaplast Baume B5+ Balm therapy initiation

by the Fitzpatrick scale, indicating a predominance of individuals with fair skin that burns easily and tans minimally. Over 90% of the participants were referred and included in the study by a dermatologist, underscoring the clinical relevance and rigor of the patient selection process. This diverse study population facilitated a comprehensive assessment of Cicaplast Baume B5+ Balm efficacy across various dermatological conditions, while also accounting for differences in age, gender, and skin type.

Initial visit

Notably, 78.4% (n = 292) of the patients were prescribed Cicaplast Baume B5+ Balm as part of their skin care regimen for treating superficial skin trauma, managing contact dermatitis, or as an adjuvant in the treatment of actinic keratosis (Fig. 1). The lesions were located most often on the face (33%), followed by the extremities (20%), hands (19%), trunk (15%), and genital and anal areas (15%). Nearly half of the subjects (45%) had lesions occupying an area of 3–10 cm², and 30% of patients had lesions that exceeded 10 cm² in size. Detailed information for Cicaplast Baume B5+ indications is summarized in Table 2. The majority of patients were instructed to apply Cicaplast Baume B5+ twice daily (42.5%) for two weeks. At the initial visit, 96% of subjects had at least mild erythema, 78% experienced scaling, 57% had superficial skin fissures, 55% had skin edema, 42% showed skin thickening, and 36% presented with dyspigmentation (both hyperpigmentation and hypopigmentation) (Fig. 2). When assessing the symptoms associated with skin lesions, patients most frequently complained about burning sensation (90%) and skin tightness (85%). Additionally, 68% of respondents felt pain, and 62% reported a tingling sensation (Fig. 3).

Table 2. Detailed indications for Cicaplast Baume B5+ Balm in the study population

Indication for use (n = 292)	Percent [%]
Dry eczema	28.8
Nonspecific dermatitis with irritation and cracking	22.6
Cheilitis and/or angular cheilosis	11.3
Skin irritation due to abrasion	7.5
Inflammation of the vulva or balanoposthitis	7.5
Diaper dermatitis (without exudative lesions)	6.2
Superficial skin fissures	5.8
Superficial skin burns	4.5
Adjuvant therapy for the treatment of solar keratosis (imiquimod, 5-fluorouracil)	4.5
Other indications (e.g. atopic dermatitis, other forms of dermatitis, acne, stretch marks)	11.3
Post-treatment use (n = 78)	
Non-invasive/no dermabrasion (laser treatment 37.2%; cryotherapy 14.1%; superficial peels 12.8%; photodynamic therapy 7.7%)	71.8
Invasive/dermabrasion (Q-switched lasers, ablative CO ₂ laser, electrocoagulation, curettage, microneedling)	24.4
Other (e.g. Dermapen, Suprathel)	3.8

Efficacy

The study yielded promising results, demonstrating the efficacy of Cicaplast Baume B5+ in improving the clinical condition of patients with various dermatological issues. An improvement in the clinical condition of the subjects was observed in 84% of patients using Cicaplast Baume B5+, with 27% showing significant improvement by more than one degree. The improvement was particularly evident among

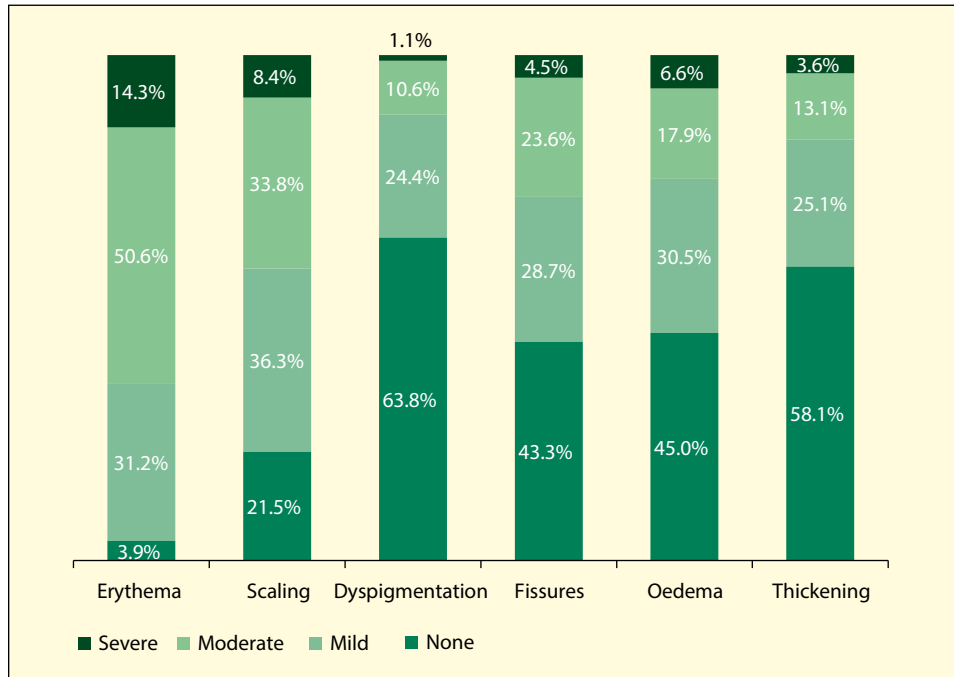


Figure 2. Dermatological symptoms presented by patients included in the study

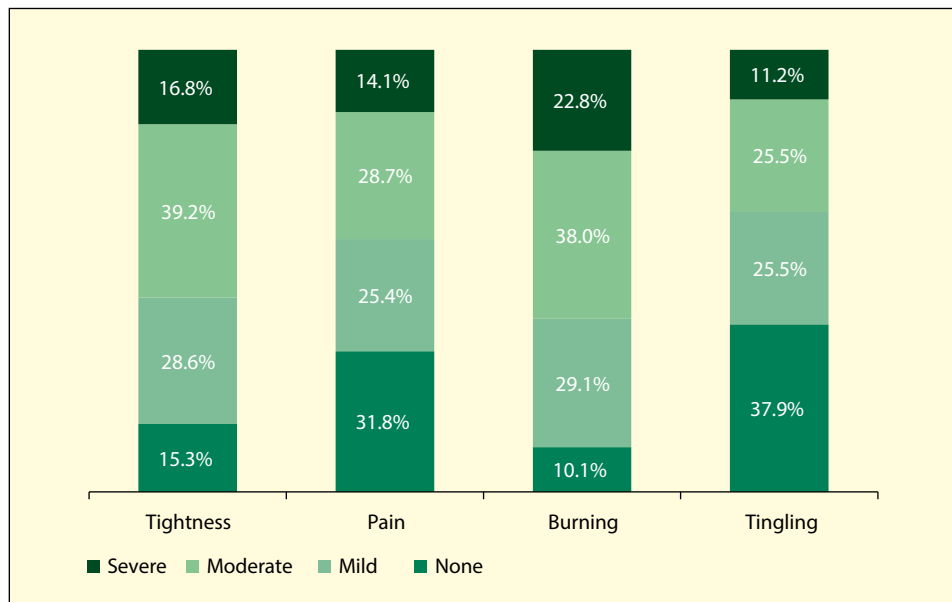


Figure 3. Evaluation of the cutaneous sensations and their severity reported by study participants

those patients whose clinical condition was assessed as moderate or severe at the initial visit, with improvement observed in almost all such subjects (93.4–96.2%).

For each of the symptoms examined at the initial and follow-up visit (erythema, desquamation, dyspigmentation, fissures, edema/thickening), statistically significant improvement was observed among patients after the

application of Cicaplast Baume B5+. Specifically, a reduction in erythema was observed in 84.5% of subjects, desquamation in 69.5%, fissures in 54.0%, edema in 52.7%, and dyspigmentation in 25.5% (Tab. 3). Furthermore, for 58% of patients, no visible marks were observed on the skin after an invasive or non-invasive procedure and after application of Cicaplast Baume B5+. However, 42.3% of subjects

Table 3. The rate of clinical symptoms before and after the treatment with Cicaplast Baume B5+ Balm

Clinical symptom	Severity	Initial visit	Follow-up visit
Erythema	Absent	3.9%	56.5%
	Mild	31.2%	39.0%
	Moderate	50.6%	4.2%
	Severe	14.3%	0.3%
Desquamation	Absent	21.5%	72.1%
	Mild	36.3%	25.4%
	Moderate	33.8%	2.2%
	Severe	8.4%	0.3%
Dyspigmentation	Absent	63.8%	79.9%
	Mild	24.4%	16.4%
	Moderate	10.6%	3.4%
	Severe	1.1%	0.3%
Fissures	Absent	43.3%	92.1%
	Mild	28.7%	6.2%
	Moderate	23.6%	1.4%
	Severe	4.5%	0.3%
Oedema	Absent	45.0%	95.7%
	Mild	30.5%	3.4%
	Moderate	17.9%	0.9%
	Severe	6.6%	0.0%

still had predominantly mild erythema after the previous medical procedures.

The overall evaluation of the effectiveness of Cicaplast Baume B5+ is high. In the case of 96.6% of patients, doctors rated it as good or excellent. The patients themselves were similarly satisfied, with 96% of those surveyed rating the effectiveness of treatment with Cicaplast Baume B5+ as at least good.

These results underscore the potential of Cicaplast + B5+ as an effective treatment for enhancing skin healing and managing symptoms associated with dermatological conditions. The significant improvement noted in patients with more severe initial conditions highlights its robust regenerative properties.

Patients' satisfaction and product tolerability

Almost all surveyed patients (98.4%) reported satisfaction with the soothing effect of Cicaplast Baume B5+ Balm and the comfort of using the product. Patients most appreciated the reduction in discomfort (97.4%), the soothing of the skin (97.4%), and the relief of skin irritation (97.4%).

Additionally, almost all surveyed patients agreed that Cicaplast Baume B5+ Balm is easy to apply (98.9%), has

a pleasant texture (98.3%), and is gentle on the skin (97.7%). These high levels of patient satisfaction highlight the product's efficacy and user-friendliness, making it a preferred choice for managing various dermatological conditions.

DISCUSSION

The findings of this study underscore the significant regenerative properties and high patient satisfaction associated with the use of Cicaplast Baume B5+. The observed improvements in clinical conditions and the positive feedback from patients align with existing literature, highlighting the balm's effectiveness in promoting skin healing and managing dermatological symptoms.

Regenerative properties

Cicaplast Baume B5+ demonstrated substantial efficacy in enhancing skin healing, as evidenced by the improvement in 84% of the patients. The significant improvement observed in patients with moderate to severe conditions (93–96%) further corroborates the findings of Li et al. [4], who reported similar outcomes in a study on post-procedural skin recovery, along with another Chinese observational study [5].

The balm's ingredients, including panthenol (pro-vitamin B₅), madecassoside, and zinc, contribute to its regenerative properties. Panthenol is known for its ability to improve hydration, reduce transepidermal water loss, and maintain skin elasticity, which are crucial for effective wound healing [6, 7]. Madecassoside, derived from *Centella asiatica*, has been shown to promote fibroblast proliferation and collagen synthesis, enhancing the skin's repair mechanisms [8]. Zinc, with its anti-inflammatory and antimicrobial properties, further supports the healing process by preventing infections and reducing skin irritation [9]. Brandt et al. [9] highlighted zinc's effectiveness in treating acne and other skin conditions, reinforcing its relevance in formulations aimed at repairing and soothing irritated skin. Additionally, maintaining or restoring a healthy microbiome is crucial for optimizing skin regeneration. Ingredients like panthenol, madecassoside, and zinc, found in products such as Cicaplast Baume B5+, not only help to soothe the skin and reduce inflammation but also support the skin barrier, creating an environment conducive to beneficial microbial growth. This, in turn, enhances the skin's natural healing processes.

Maintaining or restoring a healthy microbiome is crucial for optimizing skin regeneration. Ingredients like zinc, found in products such as Cicaplast Baume B5+, not only help to soothe the skin and reduce inflammation but also support the skin barrier, creating an environment conducive to beneficial microbial growth. This, in turn, enhances the skin's natural healing processes.

Recent studies have explored the role of the microbiome in wound healing, suggesting that probiotic and prebiotic skincare products can help restore microbial balance, reduce the colonization of harmful pathogens, and support the skin's defense mechanisms [10]. This approach is particularly relevant in post-procedure care, where the skin's barrier function is compromised, and the risk of infection is higher.

The importance of the microbiome in skin health and regeneration is supported by a growing body of evidence, underscoring the need to consider microbiome-friendly ingredients and practices in dermatological treatments. As the field continues to evolve, incorporating microbiome-focused strategies will likely become a standard in promoting skin recovery and preventing complications after dermatological interventions [10].

Symptom reduction

The study also highlighted significant reductions in symptoms such as erythema or desquamation. These findings are consistent with research among breast cancer patients that demonstrated the efficacy of topical treatment (e.g. with Cicaplast Baume B5+) in reducing dermatological adverse effects after radiotherapy [11]. The balm's ability to alleviate symptoms and enhance skin recovery makes it a valuable treatment option for various dermatological conditions, including contact dermatitis and actinic keratosis.

Patient satisfaction

Patient satisfaction with Cicaplast Baume B5+ was remarkably high, with 98.4% of surveyed patients reporting satisfaction with its soothing effects, speed of skin restoration, and ease of use. Moreover, patient satisfaction and the additional positive impact of dermocosmetic might influence the patient's adherence to prescribed treatment [12].

Limitations

The relatively short follow-up period of 14 days may not fully capture long-term effects or rare adverse reactions. Furthermore, the study lacks a control group, making it difficult to isolate the effects of Cicaplast Baume B5+ from other factors influencing skin healing.

CONCLUSIONS

In conclusion, Cicaplast Baume B5+ exhibits robust regenerative properties and high patient satisfaction, making it an effective treatment for a range of dermatological conditions. The balm's ability to significantly reduce symptoms and enhance skin healing, coupled with its positive reception among patients and healthcare providers, underscores its value in dermatological care. Future studies could further explore its long-term benefits and potential applications in other skin conditions.

Article information and declarations

Data availability statement

Data is contained within the article.

Ethics statement

The study was conducted according to the guidelines of the Declaration of Helsinki.

Author contributions

Writing — original draft preparation — JS; review and editing — JS, AR, DW-B, IW, AR; supervision — IW. All authors have read and agreed to the published version of the manuscript.

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None.

Conflict of interest

JS has been a sub-investigator in clinical trials sponsored by Incyte, Kymab Limited, Galderma, AbbVie, LEO Pharma, Argenx, Syneos Health, and Celltrion. AR has worked as a consultant or speaker for AbbVie, Bioderma, Celgene, Chema-Elektromet, Eli Lilly, Galderma, Janssen, LEO Pharma, Medac, Menlo Therapeutics, Novartis, Pierre-Fabre, Sandoz, and Trevi, and participated as principal investigator or sub-investigator in clinical trials sponsored by AbbVie, Arcutis, Drug Delivery Solutions Ltd, Galderma, Genentech, Janssen, Kymab Limited, LEO Pharma, Menlo Therapeutics, MetrioPharm, MSD, Novartis, Pfizer, and Trevi. DW-B is an employee of L'Oréal. IW declares no conflict of interest.

Supplementary material

None.

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