



# New Topical Therapy for Moderate Psoriasis: An Open-Label, Pilot Study

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## ABSTRACT

Psoriasis is a persistent, recurring condition characterized by numerous complications. Currently, there is no definitive cure for psoriasis, and treatments typically provide temporary relief of symptoms. The present study aimed to develop a new topical treatment for moderate psoriasis. Patent 202030824, an innovative cream for psoriasis local treatment, was issued by the Spanish Ministry of Industry, Trade, and Tourism. This product is called "Psorisbye," and it's a foamy lotion that contains clobetasol, propylene glycol, spironolactone, milk-peptide complex, and papaverine hydrochloride. We report on five cases of mild psoriasis that responded well to our recently developed foamy lotion treatment. Our pilot study is an open-label intervention study involving patients with moderate psoriasis. Initially, each patient underwent a comprehensive assessment, encompassing a thorough history-taking and clinical examination. Next, instructions were given to each patient to use our recently developed foamy lotion once a day for a week, using a total of 120 ml of the product during this time. The patients had a follow-up evaluation in the outpatient clinic following 7 days of local application. Every patient noted a remission of scaling lesions and claimed a significant reduction in itching sensations. The mean pre-treatment PASI of the patients was 20.28 (SD 6.1), while the mean post-treatment PASI was 1.8. Our preliminary investigation indicated promising results in the treatment of moderate psoriasis with "Psorisbye". Notwithstanding these encouraging results, a longer follow-up is necessary to assess the length of psoriasis remission and any possible adverse effects related to this novel topical medication.

**Key Words:** Psoriasis, Topical therapy, Psoriasis area severity index, Case series, Malaga

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## INTRODUCTION

Psoriasis is a persistent, recurring condition characterized by numerous complications. Currently, there is no definitive cure for psoriasis, and treatments typically provide temporary relief of symptoms. In many instances, systemic treatments have proven to be more effective than topical treatments. However, prolonged use of systemic treatments has been linked to various adverse events [1, 2]. While topical clobetasol cream, either alone or in combination with betamethasone, has demonstrated effectiveness in treating mild to moderate psoriasis, supplementary therapies are essential to enhance patients' satisfaction and optimize the efficacy of topical treatments [3, 4].

An innovative local therapeutic cream for psoriasis has been patented by the Spanish Ministry of Industry, Trade, and Tourism (Invention patent reference number 202030824). This novel product, called "Psorisbye," is a foamy lotion that contains propylene glycol, clobetasol, spironolactone, milk-peptide complex, and papaverine hydrochloride [5].

The present study aimed to develop a new topical treatment for moderate psoriasis. We report on the results of five mild psoriasis patients who were treated with "Psorisbye," our recently developed foamy lotion.

## MATERIALS AND METHODS

Our pilot study is an open-label intervention study

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involving five patients with moderate psoriasis. Initially, each patient underwent a comprehensive assessment, encompassing a thorough history-taking and clinical examination.

The history-taking phase gathered information such as age, gender, past medical history, psoriasis symptoms, duration of the disease, and details of medications used, both topical and systemic, for psoriasis treatment.

The clinical examination focused on identifying the site and types of psoriatic lesions, along with determining the Psoriasis Area Severity Index (PASI) score. The PASI is a metric that assesses the average redness, thickness, and scaliness of psoriatic lesions. Each of these parameters is graded on a scale from 0 to 4, and the scores are weighted based on the area of involvement [6].

Subsequently, each patient received instructions to apply our newly patented foaming lotion, "Psorisbye", once daily for one week, utilizing a total of 120 ml of the product during this period.

After 7 days of local application, the patients were re-evaluated in the outpatient clinic. During this follow-up, patients were queried about the progress of scaled lesions and any changes in itching sensation. A comprehensive examination, including a recalculated PASI score, was conducted one week after the application of "Psorisbye".

## RESULTS AND DISCUSSION

Our case series comprised five patients with moderate psoriasis. The average age of the patients was 35.4 years (SD = 11.6). The series consisted of 3 females (60%) and 2 males (40%). All patients exhibited multiple plaque lesions, with one patient presenting both multiple plaque lesions and erythrodermic psoriasis. Every patient noted a remission of scaling lesions and claimed a significant reduction in itching sensations. The mean pre-treatment PASI of the patients was 20.28 (SD = 6.1), while the mean post-treatment PASI was 1.8 (Table 1).

**Table 1.** Characteristics of psoriatic patients treated with the new foaming lotion "Psorisbye".

N.	Age in years	Gender	Type of lesions	Duration of diagnosis in years	Pre-treatment PASI	Post-treatment PASI
1	28	Male	Multiple plaque lesions and erythrodermic psoriasis	8	20.9	1.8
2	25	Female	Multiple plaque lesions	6	10.8	1.8
3	39	Female	Multiple plaque lesions and erythrodermic psoriasis	7	22	1.8
4	54	Male	Multiple plaque lesions and erythrodermic psoriasis	10	19.8	1.8
5	31	Female	Multiple plaque lesions and erythrodermic psoriasis	15	27.9	1.8

Figures 1-5 depict the lesions in the participating patients both before and one week after the application of the novel topical treatment.



a)

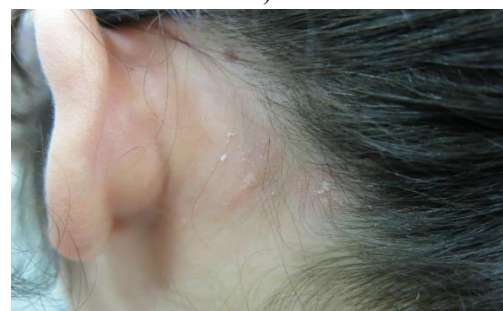


b)

**Figure 1.** Patient number one's left forearm both before and after the new topical therapy was applied.



a)

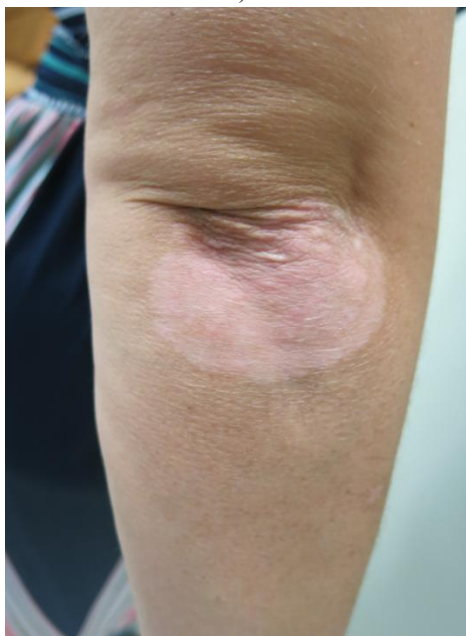


b)

**Figure 2.** The patient's left retro auricular region both before and during the administration of the novel topical medication.



a)



b)

**Figure 3.** The right elbow of patient number three both before and after the new topical therapy was applied.



a)



b)

**Figure 4.** Before and during the administration of the novel topical therapy, the left leg of patient number 4.



a)



b)

**Figure 5.** The patient's fifth leg's back, both before and after the new topical therapy was applied.

In this study, we recorded the use of "Psorisbye," a freshly created foamy lotion that was patented by the Spanish Ministry of Industry, Trade, and Tourism, in the treatment of five patients with mild psoriasis.

Scaled lesions were seen to have disappeared in all five of the research participants, and they also reported a marked

reduction in itching. The mean PASI score of the patients demonstrated a noteworthy enhancement, decreasing from 20.28 before the application of the new foaming to 1.8 after its application. This difference signifies a clear and objective improvement in the patient's condition.

In the short run, it is clear that the new foamy lotion "Psorisbye" is effective in treating mild psoriasis. This aligns with our earlier case reports on "Psorisbye," which were recently published [5, 7].

According to our research, "Psorisbye" successfully made use of the synergistic effects of clobetasol, papaverine hydrochloride, spironolactone, milk-peptide complex, and propylene glycol by carefully balancing their doses.

Propylene glycol, spironolactone, milk peptide complex, clobetasol, and papaverine hydrochloride are all included in our new foamy lotion. A popular corticosteroid for psoriasis, clobetasol is known to be beneficial in mild, moderate, and severe cases [8]. By activating potassium channels in the smooth muscles of peripheral arteries, papaverine hydrochloride acts as a strong arteriolar vasodilator [9]. By controlling sebum gland activity, sirolactone helps to lessen the seborrhic hyperproduction that is frequently seen in psoriasis [10]. The milk-peptide combination revitalizes skin cells and encourages the synthesis of fibronectin, hyaluronic acid, and collagen, which improves and softens the structure of the skin [11]. Additionally, propylene glycol facilitates skin hydration absorption, contributing to a softer skin texture [12].

## CONCLUSION

Our preliminary investigation indicated promising results in the treatment of moderate psoriasis with "Psorisbye". Notwithstanding these encouraging results, a longer follow-up is necessary to assess how long psoriasis remission lasts and whether this novel topical medication has any adverse effects.

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**Conflict of interest:** None

**Financial support:** None

**Ethics statement:** An innovative local therapeutic cream for psoriasis has been patented by the Spanish Ministry of Industry, Trade, and Tourism (Invention patent reference number 202030824). Written informed consent was obtained from the patients for treatment and publication of this case series, including accompanying images. This study was conducted following the World Medical Association's Declaration of Helsinki for research involving human subjects.

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