



Management of Psoriasis with a XemaTop Topical Compounded Formula: A Case Report

ABSTRACT

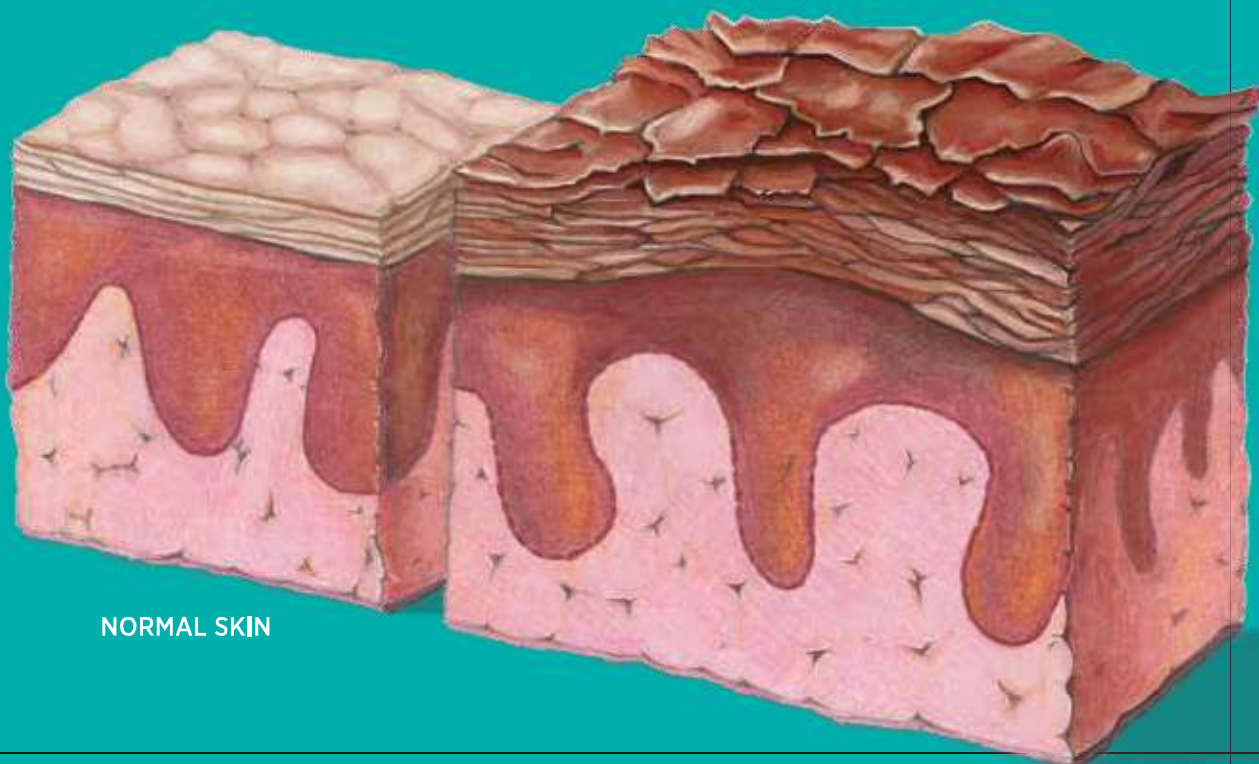
Skin conditions such as psoriasis and eczema negatively impact the patient's quality of life; the primary goal of topical treatments is to minimize the disease-specific symptoms. This case report discusses the management of two refractory psoriasis skin lesions in an adult male using a topical compounded formula. The psoriasis symptoms were assessed quantitatively using two validated research instruments, the Psoriasis Symptom Inventory, and an adapted Numeric Rating Scale. A qualitative assessment was also performed by evaluating the digital photographs taken by the patient during the course of treatment. The compounded formula containing zinc pyrithione, clobetasol propionate, and cyanocobalamin in the Professional Compounding Centers of America's proprietary base PCCA XemaTop, applied topically for three weeks, significantly reduced the patient's self-reported psoriasis symptoms and improved his overall condition by 81.2%. This successful case report is important evidence for healthcare professionals when considering new, innovative topical compounded formulas for managing skin conditions such as psoriasis and eczema.



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PSORIATIC INFLAMMATION

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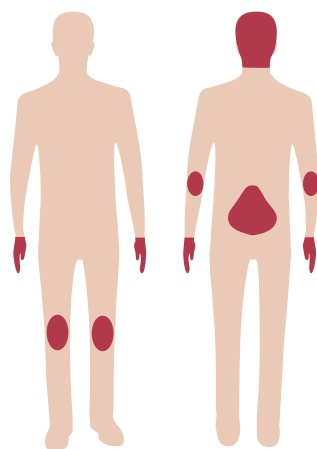


NORMAL SKIN

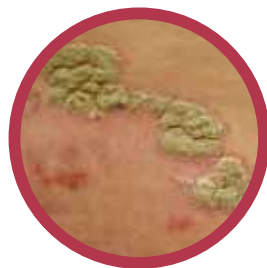
Psoriasis is a chronic autoimmune inflammatory skin disorder affecting approximately 7.5 million people in the U.S. It is characterized by skin cells that multiply up to 10 times faster than the normal rate. As the cells reach the skin's surface and die, they build up and cause raised red plaques covered with white silvery scales. About 80% of people affected by the disease have mild psoriasis and 20% have moderate to severe psoriasis. The most common form of psoriasis is chronic plaque psoriasis, which is characterized by plaques of red, inflamed, and scaly skin.^{1,2} The patches of red inflamed lesions are usually itchy and painful. They can occur anywhere on the body but are most often seen on the elbows, knees, scalp, lower back, palms, and soles of feet. Psoriasis can also be seen on the fingernails, toenails, and inside the mouth.

The exact cause of psoriasis is not completely understood but is thought to have a genetic component, with one out of three patients reporting a relative with the disease. Researchers claim that up to 10% of the general population may inherit genes that predispose them, but only 2% to 3% of those people actually develop the disease.³ Psoriasis is also expressed due to change in the immune system, specifically the white blood cells called T cells. These cells usually help protect against infection and diseases. However, in psoriasis, they are put into action by mistake and become overactive, creating inflammation and rapid cell turnover.⁴

XemaTop uses natural boswellic acid, avenanthramides from oats, phosphatidylglycerol, and a ceramide to help nourish and replenish the lamellar bilayers of the skin. This powerful synergy can help restore health into the skin's barrier that may prevent water loss, as well as reduce the appearance of red and irritated skin.



OCCURANCES ON BODY



PLAQUE PSORIASIS

Environmental factors that may also lead to flare-ups include³:

- Allergens
- Changes in climate
- Heat
- Medications
- Skin injuries

Eczema is a nonspecific term for many types of skin inflammation (dermatitis). Eczema is very common; around 30 million Americans have some form of eczema. Different types of eczema include:

- Atopic dermatitis (AD)
- Contact dermatitis
- Dyshidrotic eczema
- Hand eczema
- Neurodermatitis
- Nummular eczema
- Stasis dermatitis

All of these types of eczema can cause the skin to be red, itchy, dry, and scaly, and some may cause the skin to blister, weep, or peel. The most common type of eczema is AD, which can also be severe and long-lasting.⁵

Psoriasis, eczema, and other skin conditions that are characterized by red and itchy skin are often treated topically with various therapeutic agents. The Professional Compounding Centers of America's (PCCA) proprietary base PCCA XemaTop is a compounding base created to help deliver common active pharmaceutical ingredients (APIs) used in formulations for patients experiencing dry skin conditions such as psoriasis and eczema. XemaTop uses natural boswellic acid, avenanthramides from oats, phosphatidylglycerol, and a ceramide to help nourish and replenish the lamellar bilayers of the skin. This powerful synergy can help restore health into the skin's barrier that may prevent water loss, as well as reduce the appearance of red and irritated skin.⁶

The purpose of this case report is to discuss the management of two refractory psoriasis skin lesions, located on the patient's lower left abdomen and upper left triceps, using a topical compounded formula.

CASE REPORT

The patient is a 33-year-old Caucasian male who has had plaque psoriasis since age 19. He has mostly small plaque type psoriasis lesions scattered over 75% of his body, but the largest and worse lesions are on his back. The patient's medical history is remarkable for an allergy to penicillin and peanuts; his maternal grandmother had psoriasis; he was diagnosed with Hodgkin lymphoma when he was young and had his spleen removed, with full remission by age 18.

The patient has tried topical manufactured treatments in the past, namely: Triamcinolone Acetonide 0.05% Augmented Ointment and Desonide 0.05% Carbomer Gel. The most recent treatment was apremilast oral tablets (titrated up to 30 mg twice daily) for four months,

with only minor results. He stopped this treatment three weeks prior to initiating a new XemaTop topical compounded formula.

With direction from the pharmacist, the patient chose to apply the XemaTop topical compounded formula to two specific lesions, one on his lower left abdomen and one on his upper left arm (triceps area).

A total of 300 g were dispensed to the patient, and the formula was applied to the affected areas twice daily, once in the morning and once in the evening. The compounded formula contained zinc pyrithione 0.2%, clobetasol propionate 0.05%, and cyanocobalamin 0.07% in XemaTop topical cream (see provided formula).

Zinc pyrithione is thought to treat skin conditions (dandruff and seborrheic dermatitis) by its actions as a cytostatic agent and through its anti-fungal and anti-bacterial activity. The cytostatic actions suppress cellular growth and multiplication, resulting in a reduction in the turnover of epidermal cells also making it suitable for a hyperkeratotic state such as psoriasis. In psoriasis, there is decreased spontaneous keratinocyte apoptosis in lesional skin.^{7,8} Topical zinc pyrithione has been studied in the treatment of localized psoriasis.⁹

Topical corticosteroids are widely used in the treatment of psoriasis and AD because of their local anti-inflammatory effects. Psoriasis is commonly more difficult to treat than AD and, as a result, ultrapotent corticosteroids such as clobetasol propionate

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Rx

XEMATOP TOPICAL COMPOUNDED FORMULA APPLIED TO THE PATIENT'S PSORIASIS LESIONS

For 100 g

Zinc pyrithione (48%) min. aqueous dispersion	0.417 g
Clobetasol Propionate Micronized	0.05 g
Cyanocobalamin	0.07 g
Purified Water	5 mL
Base, PCCA XemaTop	qs 100 g

METHOD OF PREPARATION

1. Add Cyanocobalamin to Purified Water in an appropriate-size beaker. Use an amount of Purified Water that is approximately 80% of the specified amount. Mix well until dispersed and most of the solid is dissolved.
2. Add PCCA XemaTop Base in an appropriate-size electronic mortar and pestle (EMP) jar. Use an amount that is approximately 50% of the final weight.
3. Add the mixture from Step 1 to the mixture from Step 2.
4. Rinse the Step 1 beaker with Purified Water and combine the rinsing into the Step 3 EMP jar. Use an amount of Purified Water that is approximately 20% of the specified amount.
5. Add the zinc pyrithione and Clobetasol Propionate to the mixture from Step 4, then bring to the final weight with PCCA XemaTop Base.
6. Mix the mixture from Step 5 with the EMP for 2 minutes on a medium setting.
7. Process the mixture from Step 6 through an ointment mill (setting of 2) 1 time to reduce the particle size of the active ingredients and to eliminate any grittiness of the final preparation.
8. Return the mixture from Step 7 to the EMP jar and mix again for 1 minute on a low setting.
9. Package and label the preparation.

are commonly prescribed to these patients. Clobetasol propionate 0.05% may be used alone or in combination with other APIs, traditionally in an ointment vehicle, though newer, less "messy" vehicles are likely to promote treatment compliance and thus therapeutic efficacy.¹⁰

Cyanocobalamin has been effectively used topically to treat psoriasis, eczema, and AD.¹¹⁻¹³ Cyanocobalamin is a nitric oxide (NO) blocker; it neutralizes NO radicals and thus reduces the so-called nitrosative stress, which is responsible for a variety of symptoms and certain skin diseases. NO is especially suspected to be the cause of the irritations and skin changes in eczema and psoriasis.¹⁴

The patient reported that no major dietary changes were made during the course of treatment, aside from making an effort to eat healthier and cutting back on his daily intake of milk and dairy.

METHODOLOGY

Valid and reliable assessment of outcomes is essential in scientific case studies, and, therefore, the success of the compounding treatment was evaluated using two validated research instruments, the Psoriasis Symptom Inventory (PSI) and an adapted Numeric Rating Scale (NRS). A qualitative assessment was also performed by evaluating the digital photographs of the psoriasis lesions taken by the patient before, during, and after the compounding treatment. Written informed consent was obtained from the patient for publication of this case report and the accompanying digital photographs.

The PSI is a patient-reported outcome (PRO) instrument that measures the patient's perspective of the disease by assessing the severity of the following eight psoriasis symptoms:

- Itching
- Burning
- Cracking
- Flaking
- Pain
- Redness
- Scaling
- Stinging

The symptoms are scored by the patient on a 5-point Likert-type rating scale, from not at all severe (0), to mild (1), moderate (2), severe (3), and very severe (4). The sum of all individual scores gives a total score assessment, with a minimum of

0 (no psoriasis symptoms) and a maximum of 32 points (very severe psoriasis symptoms). The PSI corresponds to a validated, reproducible and responsive to change questionnaire¹⁵ that is commonly used in clinical practice. According to the U.S. Food and Drug Administration (FDA) Guidance for Industry on PRO Measures,¹⁶ this is the only psoriasis-specific PRO measure that meets all the specified criteria.¹⁷ In this prospective case study, the patient completed the PSI questionnaire twice, before initiating the treatment and following three weeks of treatment.

The NRS is a generic, unidimensional, self-reported assessment that consists of a segmented, 11-point intensity scale (from 0 to 10). The raw change and percent change are calculated taking into account the baseline and endpoint scores selected by the patient. The NRS is commonly used to assess pain,¹⁸ and it was adapted in this case study to quantify the overall severity of the psoriasis symptoms before and after the topical compounding treatment. The back of the PCCA scientific ruler (Figure 1) was used by the patient as an adapted NRS-11 in this assessment.

The digital photographs of the psoriasis lesions were taken by the patient in a standardized manner by using the same digital camera and in the same position/angle. The front of the PCCA scientific ruler (Figure 2) was used by the patient to quantify any potential changes in the length of the lesions.

As psoriasis is characterized by periods of improvement and relapse,¹⁵ a one-week, two-week, and six-week post-treatment assessment was conducted to register any fluctuating symptoms.

RESULTS AND DISCUSSION

At baseline, before initiating treatment with the compounded formula, the patient classified the redness and flaking of his psoriasis lesions as *very* severe, whereas itching and scaling were classified as severe. Flaking refers to the loss of dry skin cells, whereas scaling refers to the loss of the compacted desquamated layers of stratum corneum, commonly known as psoriasis plaques or scales.¹⁹ Redness, flaking, and scaling are the most noticeable physical symptoms of psoriasis and the ones most likely to negatively impact the patient's physical well-being. All other psoriasis-specific symptoms (e.g., burning, sting-

FIGURE 1. PROFESSIONAL COMPOUNDING CENTERS OF AMERICA'S SCIENTIFIC RULER WITH AN ADAPTED NUMERIC RATING SCALE ON THE BACK.

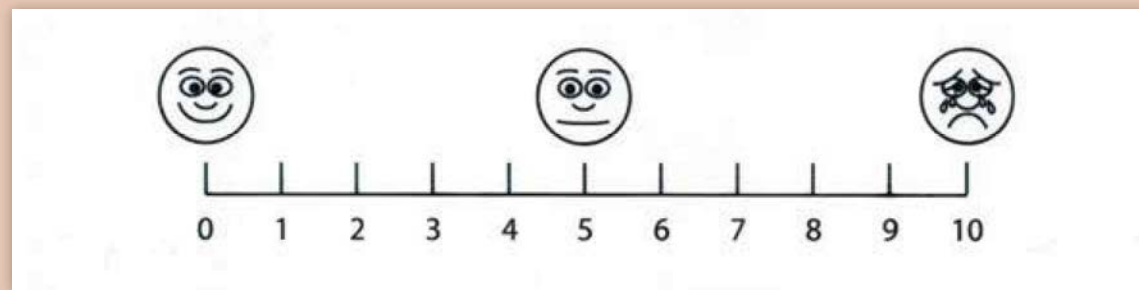
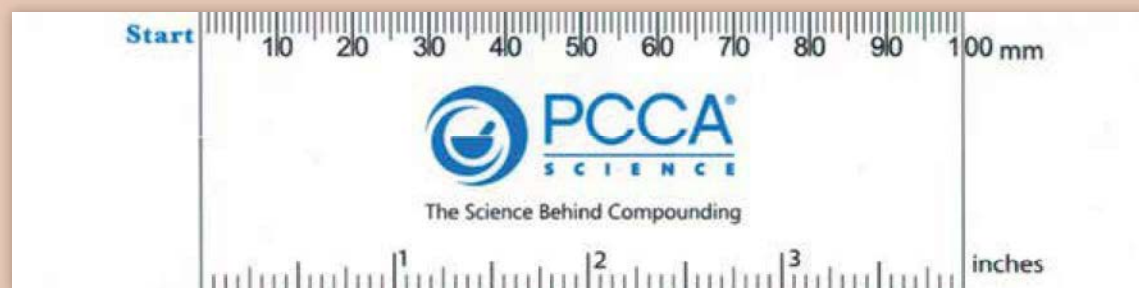


FIGURE 2. PROFESSIONAL COMPOUNDING CENTERS OF AMERICA'S SCIENTIFIC RULER WITH A 10-CM SCALE ON THE FRONT.



ing, cracking, pain) were classified as moderate, which resulted in a total score assessment of 22. Overall, the patient quantified the severity of his symptoms as 7 (out of 10), as displayed in Table 2.

Following three weeks of twice-daily application of the Xema-Top topical compounded formula, the patient reported significant improvement of his psoriasis condition at both locations—the lower left abdomen and the upper left tricep. The severity of all psoriasis-specific symptoms was reduced to 0, with the exception of redness that was classified as 2 (moderate). The best possible PSI outcome is 0, which is defined as complete recovery of the psoriasis symptoms.¹⁹ The PSI total score assessment was reduced from 22 to 2 (90.9% improvement), whereas the NRS overall severity of the psoriasis symptoms was reduced from 7 to 2 (71.4% improvement), resulting in an average percentage of improvement of 81.2% (Table 1).

The self-reported improvement of the patient's psoriasis condition at both locations is consistent with the qualitative improvements observed in the digital photographs taken before, during, and after treatment (Figures 3 through 10). After three weeks of therapy, both of the patient's lesions were reduced to flat pink smooth

patches with complete resolution of plaque. It is clear from the photographs that the skin color is the only psoriasis-symptom that was not fully resolved.

TABLE 1. BEFORE AND AFTER TREATMENT SELF-REPORTED ASSESSMENT OF PSORIASIS SYMPTOMS.

PSORIASIS-SPECIFIC PATIENT-REPORTED OUTCOME		BEFORE TREATMENT	AFTER TREATMENT
PSI	Itching	3	0
	Redness	4	2
	Scaling	3	0
	Burning	2	0
	Stinging	2	0
	Cracking	2	0
	Flaking	4	0
	Pain	2	0
	Total	22	2
NRS	Overall	7	2

DIGITAL IMAGES OF THE PATIENT'S LEFT LOWER ABDOMEN PSORIASIS LESION: BEFORE (FIGURE 3), ONE-WEEK (FIGURE 4), TWO-WEEKS (FIGURE 5), AND AFTER (FIGURE 6) THE TOPICAL COMPOUNDING TREATMENT.

FIGURE 3



FIGURE 4



FIGURE 5

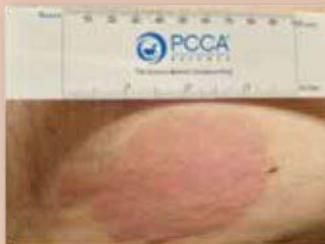


FIGURE 6



FIGURE 7



FIGURE 8



FIGURE 9



FIGURE 10



DIGITAL IMAGES OF THE PATIENT'S LEFT UPPER TRICEP PSORIASIS LESION: BEFORE (FIGURE 7), ONE-WEEK (FIGURE 8), TWO-WEEKS (FIGURE 9), AND AFTER (FIGURE 10) THE TOPICAL COMPOUNDING TREATMENT.

The patient's self-assessment is shared below:

ONE-WEEK TREATMENT (FIGURES 4 AND 8): "I have to say I am really surprised at how fast the treatment has worked on the spots. I honestly say that pictures don't do justice to how well this has worked."

TWO-WEEK TREATMENT (FIGURES 5 AND 9): "The spots have improved overall to the point of being fresh skin with no signs of the psoriasis other than areas being a different color tint compared to the skin around it."

THREE-WEEK TREATMENT (FIGURES 6 AND 10): "The treatment is still doing well. It's smooth skin and currently it is just suffering from not being tan. Redness is noticeable but it is not a problem."

ONE-WEEK POST-TREATMENT: "I did stop applying the medication to the spots I've been working with. They appear to have the same texture and appearance as when I first stopped applying the medication. I'm happy with the turnout of the treatment."

LIKewise, following a two-week and a six-week post-treatment, the patient's self-assessment was: "No relapse of the psoriasis symptoms."

Many psoriasis patients dislike the traditional ointment-based topical therapies and may either miss doses or not fill the prescriptions at all. Actually, approximately 40% of the psoriasis patients report non-adherence to topical treatments.¹⁰ The compounding base PCCA XemaTop allows for an elegant and smooth compounded formula, which was likely a key contributor to the patient's treatment compliance.

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CONCLUSION

Skin conditions such as psoriasis and eczema negatively impact the patient's quality of life, and the primary goal of topical treatments is to minimize the disease-specific symptoms.¹⁹ The efficacy of topical treatments is commonly assessed by PROs that measure the patient's self-reported symptoms, such as the PSI in psoriasis patients. This case report has demonstrated that a compounded formula containing zinc pyrithione, clobetasol propionate, and cyanocobalamin in the proprietary base PCCA XemaTop, applied topically for 3 weeks, significantly reduced the patient's self-reported psoriasis symptoms and improved his overall condition by 81.2%. This successful case report is important evidence for healthcare professionals when considering new, innovative topical compounded formulas for managing skin conditions such as psoriasis and eczema.

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