

Nutraseb™ Facial Cream: Designed to Target Seborrheic Dermatitis



By Neal Bhatia, MD

Affecting one to three percent of the general adult population worldwide, seborrheic dermatitis (SD) is a common presentation in dermatology practices.¹⁻³ While dermatologists are well aware of the condition and typically have little difficulty making a diagnosis, treatment can be a challenge. The pathogenesis of SD is multi-factorial, and traditional treatments may not target all aspects of pathogenesis.³ As such, they may have limited efficacy. Furthermore, few treatments are approved exclusively to treat SD. Formulations may not be optimized for use on the face, where SD is most common.¹ In fact, nearly 80 percent of cases of SD affect the face.^{1,3} Patient satisfaction with treatment and adherence to the regimen are important considerations when managing SD for the long term.

A new treatment for facial seborrheic dermatitis, Nutraseb™ Facial Cream is formulated specifically to target the multi-factorial pathogenesis of SD and, via these effects, its multiple symptoms.

SEBORRHEIC DERMATITIS IN REVIEW

Seborrheic dermatitis appears as thin, often well-delineated reddish or ruddy brown plaques symmetrically distributed, most commonly occurring on the face.¹⁻³ Plaques are associated with inflammation, erythema and sometimes pruritus (particularly on the scalp and in the ear canal), along with

white/yellow, dry or moist oily scales. Scales are flaky, itchy, and greasy.¹⁻³ Because SD is localized to areas with sebaceous glands, the central face is commonly affected.⁴ In fact, the face is the most common area of the body affected, meaning the condition is highly visible. Not surprisingly, patients frequently report psychological distress, low self-esteem, and embarrassment associated with the scaling and erythema associated with SD, particularly when it manifests on the face.⁴

Secondary bacterial infection is a possible complication, increasing the redness, exudate and local irritation.⁵ Although the cause of SD is unknown, key factors that play a role have been identified. Genetic predisposition, hormones, stress, illness, and exogenous factors like detergents and cold, dry weather have all been implicated in SD.⁴

Seborrheic dermatitis is more common in those who are immuno-compromised, such as in those with lymphoma, HIV/AIDS, or recipients of organ transplants, or with pre-existing neurological disorders and psychiatric disorders, including Parkinson's disease, tardive dyskinesia, epilepsy, facial nerve palsy, and depression.^{4,6} Incidence of SD is higher among individuals with significant life stress.⁴

ETIOLOGY

Etiology of adult seborrheic dermatitis is not definitive, but three factors appear to be common to the disease: sebum secretion, cutaneous microflora (specifically *Malassezia furfur*), and individual susceptibility and response.⁷ There is no clearly defined stepwise pathogenesis, and the relationship between the contributing factors is not fully understood. For example, while there is strong correlation between seborrheic dermatitis

Nutraseb™ Facial Cream is contraindicated in persons with a known hypersensitivity to any of the components of the formulation. For topical use only. Avoid contact with the eyes, not for ophthalmic use. The safety and effectiveness of Nutraseb™ has not been tested on subjects younger than age 22 years.

Keep out of the reach of children. Use only as directed. Nutraseb™ does not contain a sunscreen, use of sunscreen products and protective clothing over treated areas is recommended when exposure cannot be avoided. If condition does not improve within 10-14 days, consult a physician. Please see accompanying full prescribing information.

and sebaceous gland activity, individuals with seborrheic dermatitis may have normal sebum production.⁶

Similarly, *Malassezia furfur*—a naturally occurring yeast found on normal skin of approximately 90 percent of healthy adults, is found mainly in seborrheic regions of the body and on the scalp. The yeast metabolizes sebum, but the role of *Malassezia* in driving the development of SD is not well elucidated. *Malassezia* numbers correlate with appearance and severity of seborrheic dermatitis.

The actions of *Malassezia* on the skin appear to drive an inflammatory skin response and aberrant keratinocyte differentiation, resulting in the appearance of SD symptoms.⁶

There is also evidence that individual predisposition and host interaction with *Malassezia* contribute to SD. Factors contributing to susceptibility include sebaceous activity, *Malassezia* colonization, lack of epidermal barrier integrity, host immune response, neurogenic factors, emotional stress, and nutrition.⁶

Treatments marketed to manage facial SD may not be optimized. Although corticosteroids have been used historically to manage the symptoms of SD, their use may not be ideal for facial SD. Evidence suggests that recurrence or rebound is more common following treatment with topical corticosteroids compared to other interventions.² Additionally, caution is advised when using topical corticosteroids on the face, due to concerns about inducing skin atrophy or ocular side effects. Topical anti-fungal therapies, on the other hand, tend to target only one aspect of SD pathogenesis.

TOWARD AN EFFECTIVE THERAPY

An effective topical therapy for SD should be designed to reduce the severity of all symptoms associated with the condition: erythema, scaling, excess sebum, stinging, and itching. It should also protect the underlying skin as it heals and regenerates and minimize the rate of recurrence.

A multi-targeted therapy that has anti-inflammatory, anti-fungal, anti-sebum, and anti-scaling properties is ideal.

Nutrased™ Facial Cream is a prescription cream indicated to manage and relieve the signs and symptoms of seborrhea and seborrheic dermatitis, such as itching, erythema, scaling, and pain. Nutrased™ Facial Cream helps relieve dry, waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process. It targets all four aspects of SD: inflammation, fungus, sebum, and scaling. Importantly for a product to be used on the face, Nutrased™ Facial Cream has a pleasing texture that spreads and absorbs well.

Nutrased™ Facial Cream confers anti-inflammatory properties. However, it is non-steroidal, thereby obviating these concerns.

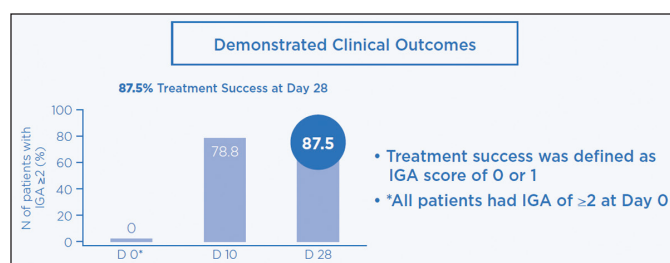


Figure 1

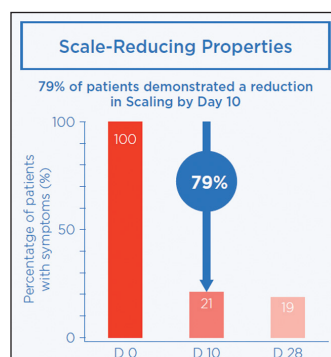


Figure 2

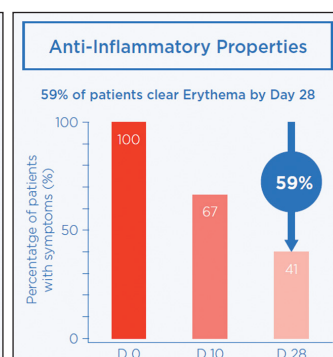


Figure 3

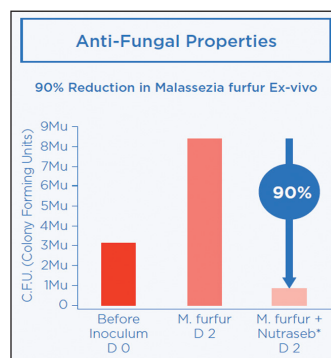


Figure 4

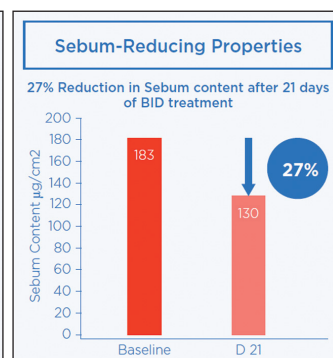


Figure 5

The clinical efficacy of Nutrased™ Facial Cream was established in a prospective, randomized, controlled, double-blind, multicenter study in which 33 patients with mild facial seborrheic dermatitis received Nutrased™ Facial Cream.⁸ Patients were instructed to apply Nutrased™ Facial Cream twice a day (morning and evening) for 28 days. Severity of SD was assessed using the Investigator's Global Assessment (IGA) score (5 item score: 0—none; 1—almost disappeared; 2—mild disease; 3—moderate disease; 4—severe disease). All patients had a baseline IGA score of 2. Treatment success was defined as IGA score ≤ 1.

Nutrased™ Facial Cream is contraindicated in persons with a known hypersensitivity to any of the components of the formulation. For topical use only. Avoid contact with the eyes, not for ophthalmic use. The safety and effectiveness of Nutrased™ has not been tested on subjects younger than age 22 years.

Keep out of the reach of children. Use only as directed. Nutrased™ does not contain a sunscreen, use of sunscreen products and protective clothing over treated areas is recommended when exposure cannot be avoided. If condition does not improve within 10-14 days, consult a physician. Please see accompanying full prescribing information.

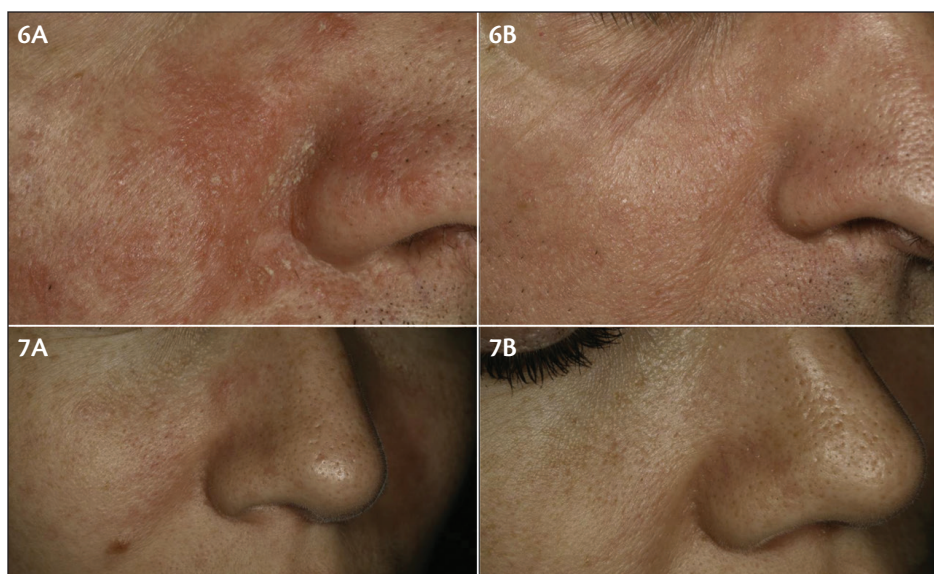


Fig 6a, 7a: Trial subjects at baseline. Note characteristic appearance of SD.

Fig 6b, 7b: After treatment.

Treatment success rates were 78.8 percent at Day 10 and 87.5 percent at Day 28.

By Day 10, 24.2 percent of subjects had no symptoms, based on IGA scores, and 54.5 percent of subjects' symptoms had almost disappeared. By Day 28, 56.3 percent of subjects were symptom-free, and 31.2 percent of subjects' symptoms had almost disappeared. (Fig. 1-3)

The anti-fungal action of Nutraseb™ Facial Cream has been shown in an ex-vivo model.⁸ In this trial, a single application of Nutraseb™ Facial Cream was associated with a significant decrease in *Malassezia furfur* colonies compared to non-treatment. (Fig. 4)

In a study specifically assessing the cosmetic efficacy and cosmetic quality of Nutraseb™ Facial Cream among 20 subjects with SD, use of Nutraseb™ Facial Cream was associated with a 27 percent reduction in sebum content and treatment was “very well tolerated” at Day 21.⁸ (Fig. 5)

A pilot, prospective evaluation of the clinical efficacy and hydration of Nutraseb™ Facial Cream for facial seborrheic dermatitis showed similar results.⁸ Twelve adult patients with mild to severe SD applied Nutraseb™ Facial Cream to the face twice daily for two weeks. In this study, subjects showed improvement in SD symptoms by day 8, resulting in an average 95 percent reduction in IGA scores.

In this study, skin hydration was assessed as a secondary

endpoint. Based on both corneometry and Skicon measures, use of Nutraseb™ Facial Cream was associated with a significant improvement in skin hydration at one hour, with statistically greater hydration over baseline maintained through six hours.

Nutraseb™ Facial Cream has been demonstrated to be noncomedogenic; its comedogenic potential was assessed in vivo under normal usage conditions. In the study that confirmed lack of comedogenicity, subjects reported very good cosmetic outcomes.

Additionally, Nutraseb™ Facial Cream was assessed for the potential to induce photosensitivity or phototoxicity. There was no evidence of phototoxicity or photoallergic potential—an important consideration for a product intended for use

on the face. Nonetheless, patients are advised to apply sunscreen daily while using Nutraseb™ Facial Cream.

TOPICAL EFFICACY; BACKED BY EVIDENCE

Nutraseb™ Facial Cream was developed specifically to improve the symptoms of seborrheic dermatitis by targeting the underlying factors that drive the skin condition. It has documented anti-fungal, anti-inflammatory, anti-sebum, and anti-erythema properties. Data show that the formulation is effective for reducing signs and symptoms of seborrheic dermatitis with no known potential for photoallergy or phototoxicity. It is non-comedogenic, and well suited for facial application.

Given the prevalence of SD and its impact on patients, the availability of a specifically designed, proven treatment option is an important therapeutic development. ■

1. Peyri J, Leonart M; Grupo español del Estudio SEBDERM. [Clinical and therapeutic profile and quality of life of patients with seborrheic dermatitis]. *Actas Dermosifiliogr*. 2007 Sep;98(7):476-82.
2. Del Rosso JQ. Adult seborrheic dermatitis: a status report on practical topical management. *J Clin Aesthet Dermatol*. 2011 May;4(5):32-8.
3. Goldenberg G. Optimizing treatment approaches in seborrheic dermatitis. *J Clin Aesthet Dermatol*. 2013 Feb;6(2):44-9.
4. Medline Plus medical encyclopedia Web site. Seborrheic dermatitis. <http://www.nlm.nih.gov/medlineplus/ency/article/000963.htm>.
5. Borda LJ, Wikramanayake TC. Seborrheic Dermatitis and Dandruff: A Comprehensive Review. *J Clin Invest Dermatol*. 2015 Dec;3(2).
6. Bhatia N. Treating seborrheic dermatitis: review of mechanisms and therapeutic options. *J Drugs Dermatol*. 2013 Jul 1;12(7):796-8.
7. Picardo M, Cameli N. Seborrheic dermatitis. In: Williams H, et al. editors. *Evidence-Based Dermatology*. Second Edition. Malden, Massachusetts: Blackwell Publishing; 2008. pp. 164–70.
8. Data on file. Morristown, NJ: ISDIN Corp.; 2017.

Nutraseb™ Facial Cream is contraindicated in persons with a known hypersensitivity to any of the components of the formulation. For topical use only. Avoid contact with the eyes, not for ophthalmic use. The safety and effectiveness of Nutraseb™ has not been tested on subjects younger than age 22 years.

Keep out of the reach of children. Use only as directed. Nutraseb™ does not contain a sunscreen, use of sunscreen products and protective clothing over treated areas is recommended when exposure cannot be avoided. If condition does not improve within 10-14 days, consult a physician. Please see accompanying full prescribing information.

Nutraseb™

Facial Cream



Rx Only

DESCRIPTION

NUTRASEB™ Facial Cream is a steroid-free, fragrance-free, water-based emulsion for the management of seborrhea and seborrheic dermatitis.

INDICATIONS FOR USE

Under the supervision of a healthcare professional, NUTRASEB™ Facial Cream is indicated to manage and relieve the signs and symptoms of seborrhea and seborrheic dermatitis, such as itching, erythema, scaling and pain. NUTRASEB™ Facial Cream helps relieve dry, waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

CONTRAINDICATIONS

NUTRASEB™ Facial Cream is contraindicated in persons with a known hypersensitivity to any of the components of the formulation.

WARNINGS

Use only as directed. **Keep out of the reach of children.** Avoid contact with the eyes. For topical use only. Not for ophthalmic use. The safety and effectiveness of this product has not been tested on subjects younger than age 22 years.

PRECAUTIONS AND OBSERVATIONS

Use NUTRASEB™ Facial Cream only as directed.

NUTRASEB™ Facial Cream is non-toxic. It is for external use only and should not be ingested or taken internally.

NUTRASEB™ Facial Cream does not contain a sunscreen. Use of sunscreen products and protective clothing over treated areas is recommended when exposure cannot be avoided.

If condition does not improve within 10-14 days, consult a physician.

INSTRUCTIONS FOR USE

Apply NUTRASEB™ Facial Cream to the affected skin areas 2 to 3 times a day (or as directed by physician), and massage gently into the skin. If the skin is broken, cover with a dressing of choice.

The product from each container should only be applied to a single patient to prevent contamination. Discard after 6 months once tube is opened.

INGREDIENTS

Water, Glycerin, Acetamide MEA, Isodecyl Neopentanoate, Cyclopentasiloxane, Pentylene Glycol, Cetyl Alcohol, Cyclohexasiloxane, Sclerotium Gum, Zinc PCA, Piroctone Olamine, Polyacrylamide, Polymethyl Methacrylate, Butylene Glycol, Stearyl Glycyrretinate, C13-14 Isoparaffin, Glyceryl Stearate, PEG-100 Stearate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Sodium Hydroxide, Laureth-7, Biosaccharide Gum-2, Disodium EDTA, Hydroxyphenyl Propamidobenzoic Acid, Ascorbyl Palmitate.

HOW SUPPLIED

NUTRASEB™ Facial Cream is available in 2 x 50g tubes (69494-200-24) and 4g professional sample tubes (69494-200-04).

STORAGE

Store at controlled room temperature 59°F – 86°F (15°C – 30°C). Do not Freeze.



Nutraseb™ ©2016 ISDIN Corp.
Manufactured in Spain for
ISDIN Corp.
Morristown, NJ 07960
862-242-8129
www.isdin.com/us