The majority of the dermatides that we as dermatologists treat are chronic or persistent, either as a direct consequence of the pathogenesis of the disease (such as barrier dysfunction implicated in atopic dermatitis (AD) and irritant contact dermatitis (ICD)) or recurrent exposure to triggers (such as workplace exposure to an allergen or irritant). Frustration with therapy is common among treating physicians and affected patients. It usually does not develop during the acute management of an initial presentation, as numerous effective therapies are available to quell inflammation and improve symptoms in a wide proportion of patients. Rather, dissatisfaction grows as patients are forced to taper and withdraw topical corticosteroids and/or topical immunomodulators (TIMs), and the dermatitis in question recurs over time.

In recent years “barrier-repair” creams, topical skin protectants, and other moisturizing formulations intended to forestall dermatitis recurrence have helped dermatologists prolong clearance while decreasing patients’ exposure to topical corticosteroids and/or topical immunomodulators (TIMs), and the dermatitis in question recurs over time.

In a study to assess the moisturizing effects of Neosalus, investigators recruited 24 patients with AD and 22 healthy controls. The AD patients underwent a two-week washout period. Clinically non-eczematous skin on the volar aspect of the forearm of the AD patients and the healthy controls was subjected to non-invasive measurements of TEWL and hydration (electrical capacitance and electrical impedance). Barrier function and hydration were abnormal in the skin of AD patients compared with controls. All subjects applied the topical formulation to the volar aspect of one forearm (the contralateral side served as a control) two or three times daily for three weeks.

The non-invasive measures were repeated on days 10 and 21, showing that treatment was associated with an increase in capacitance, no change in TEWL, and no impairment of barrier function. Moreover, among AD patients, certain impedance indices trended towards normal.

The foam is an aqueous emulsion containing stearic and palmitic acids, long-chain fatty acids normally present in the epidermis. Fatty acids are necessary to generate the hydrophobic intercellular lamellae of the stratum corneum which provide a barrier to water loss. Propylene glycol and glycerin are hygroscopic agents that draw water into the stratum corneum and hydrate the skin. Dimethicone is an occlusive agent and moisturizer that locks moisture in the stratum corneum.
and acts as a physical barrier to external irritants.

Neosalus water-lipid based foam formulation may be an attractive option for many patients. While barrier-repair and/or protective creams have been shown to be effective,6,7,8 they may not be cosmetically acceptable for certain patients or application sites. Compared to creams, the foam may be preferable for application to hair-bearing areas, larger surface areas, and intertriginous areas. While patients may be accustomed to applying creams to the hands, some may prefer the foam for use on the hands, as it absorbs rapidly and leaves no residue on the skin. This may be particularly true of patients who apply a product prior to putting on gloves.

Studies demonstrate excellent tolerability for Neosalus; only four adverse events (AEs) developed in clinical trials involving 161 patients. All AEs were reversible, and none was serious. Since the product went on the market in Europe 10 years ago, only five adverse events of local intolerance have been reported.9

**Barrier Restoration and Protection**

Perhaps the most attractive feature of Neosalus is skin protection benefits in addition to barrier restoration. The foam delivers naturally occurring components to viable epidermis to enhance barrier repair. A recent review highlighted the benefit of topical skin protectants to diminish occupational and home exposure to irritants and allergens. The authors make the important distinction that these formulations should not be used alone as primary protection from high-risk exposures (such as to corrosive chemicals). Patients using a topical protectant like Neosalus should still seek to avoid or minimize exposure to known irritants and employ physical barriers (such as gloves or clothing) in order to maximize protection.

The formulation features dimethicone, which, in addition to occluding the skin to lock moisture in the stratum corneum, also protects the skin from allergens and irritants. One study involving 20 subjects investigated the protection provided by the formulation against sodium laureyl sulfate (SLS), a common skin irritant, and urishiol, the allergen found in the resin of poison ivy and poison oak plants.10 While inhibition of reaction to urishiol was minimal, protection against SLS was very good. Irritancy on the treated side was at least 50 percent lower than on the control sides.

Among 28 patients with chronic allergic and/or irritant chronic hand dermatitis who completed one study, regular use of the foam (at least three times daily) for six weeks led to improvement of Physician Global Assessment (PGA) scores for 70 percent of subjects.11 The Investigator’s average initial global assessment score was 6.13 at baseline and 3.68 at the conclusion of the study. Subjects were permitted to use topical corticosteroids throughout the course of the study, and use was recorded. Over the six-week study period, use of topical corticosteroids decreased in 53.6 percent of subjects.

Data on file with Quinnova confirm the skin protection effects of the topical formulation for patients with incontinence-related irritation dermatitis. Twenty-two incontinent patients in a long-term care setting had erythema with intact skin (n=17) or with mild excoriation (n=5) at baseline. Following 14 days of application of Neosalus to the right buttock (the left was untreated), erythema resolved in 17 subjects.

**Clinical Role**

Topical steroids remain the mainstay of treatment for most dermatides, but they are associated with possible adverse effects, the most common of which is skin atrophy.12 Risk of adverse events is higher in pediatric and geriatric populations, and super-potent corticosteroids are generally avoided in patients under age two. To limit the development of adverse events in symptomatic management of dermatides, topical corticosteroid use is usually limited to short courses of therapy.

When topical immunomodulators reached the market, they were touted as an alternative to topical corticosteroids. They have been demonstrated effective for AD and other dermatides, such as inverse psoriasis,13 though they typically have a longer onset of action than do topical corticosteroids. However, data regarding the safety of long-term use of topical immunomodulators are limited to six-to-12-month study periods.14 While the dermatology community generally accepts that these agents can be used safely for relatively long periods, the FDA’s decision to add a black box warning about risk of malignancy has caused many clinicians to limit long-term application. This reaction is largely in response to concerns expressed by patients and parents. Topical immunomodulators are not indicated for use in patients under age two.

Neosalus is indicated for use as monotherapy or adjunctive therapy in the management of AD, ICD and other dermatoses for patients of any age. As monotherapy, it has been shown effective for mild to moderate AD and ICD. It may also be used in combination with standard topical or systemic therapy, including topical corticosteroids since it has no known drug interactions.

Neosalus should be applied to affected areas three times a day, and should be rubbed into the skin until fully absorbed.

Given actual and theoretical safety concerns associated with standard topical therapies for dermatides, as well as practical concerns, such as limited cosmesis, associated with currently
available barrier and/or protection creams and emollients, an effective barrier-repair and protection foam is a welcome treatment option both for acute management and long-term maintenance of dermatides. It may prove to be an important alternative to topical corticosteroids and topical immunomodulators for certain patients. Consider, for example, AD on the face and neck in children; areas where corticosteroids must be used with caution. Neosalus may be a primary monotherapy option to consider for this presentation. Adding it to the treatment regimen can help reduce the use of topical corticosteroids in chronic hand dermatitis thus minimizing steroid related adverse effects.

Finally, as a skin protectant, a topical foam formulation that can augment barrier methods and avoidance strategies to limit exposure to irritants and allergens may enhance compliance and help to break the cycle of exposure and flare.

Dr. Bikowski has served on the Advisory Board and Speaker’s Bureau and been a consultant to Quinnova.

9. Data on file