MEDCO FORUM®

PRESENTING INNOVATIVE PRODUCTS & SERVICES TO HEALTHCARE PROFESSIONALS

VOLUME 13 NUMBER 3 MAY 2006

REPRINT

New MimyX® Cream For Atopic Dermatitis Symptom Relief

Shown To Extend Remission With Adjunctive Use

Atopic dermatitis (AD) symptoms are estimated to affect as many as 15 million people and up to 20% of infants and young children in the U.S. (*1*). AD impacts the patient and family medically and psychosocially, and can be a financial burden, as well (*2*). Costs may be up to $2,000 per patient annually, and the direct cost of AD in the U.S. is nearly $1 billion per year (*2*).

AD also can affect the quality of life for sufferers (*1*). Parents may have difficulty preventing young children from scratching and rubbing the skin, which may result in stressful situations that affect the entire family. Older children may have social problems at school and suffer emotional stress due to the appearance of the areas affected with AD. In addition, the itch-scratch cycle often disrupts sleep for many patients, which can negatively impact school and work attendance and performance (*1*).

In normal skin, the outer layer acts as a protective barrier. However, AD causes dry itchy skin, which leads to scratching, which, in turn, irritates the skin and disrupts the protective barrier. Moisture is lost and the irritated and inflamed skin becomes more vulnerable to irritants and triggers, which leads to flares of AD.

MimyX Cream Repairs and Restores Skin Barrier Function

MimyX Cream, cleared in 2005 for the management of AD symptoms, has been shown to be safe and effective for both pediatric and adult patients (*3*). *MimyX Cream* helps repair the skin barrier by mimicking healthy skin composition and replenishing lipids deficient in atopic skin (*4*). In fact, in a trial with 30 healthy volunteers *MimyX Cream* trended to reduce transepidermal water loss, a measure of barrier repair, more than Atopiclair™ and Eucerin® (*4*).

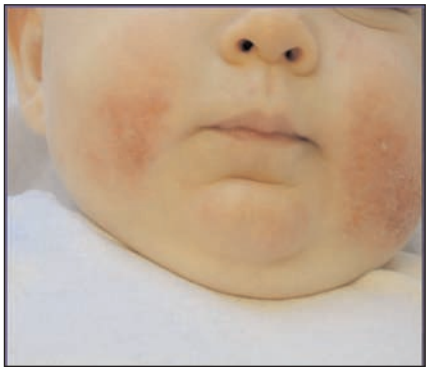
Study Shows Outstanding Symptom Relief and Improved Skin Appearance

A multicenter, international cohort study involving 2,456 patients with mild to moderate AD evaluated the effect of *MimyX Cream* on dryness, erythema, lichenification, excoriation, scaling, and itching over a 38-day period (*3*). All symptoms were improved significantly ($p<0.001$) by *MimyX Cream*, as compared to baseline (at study start, 24% of patients were on topical corticosteroids, 12% were on topical immunomodulators, 17% were on systemic antihistamines, and 79% were on other skin care creams) (*3*). Furthermore, study participants reported a 60% improvement in sleep from baseline to study conclusion ($p<0.001$) (*3*).

Importantly, *MimyX Cream* reduced the need for additional therapies. In the 545 patients on topical steroid creams at study start, there was a 62% reduction in the use of topical steroids ($p<0.001$), 34% of patients discontinued topical steroids, and 12% of patients switched to lower-potency topical steroids. Of the 255 patients on topical immunomodulators, 20% were able to discontinue their use, and of the 369 patients on systemic antihistamines, 39% were able to discontinue their use. Of those patients not using additional therapies at baseline, only 3.2% initiated topical steroid use (n=911), 2.5% initiated TIM use (n=1631), and 3.8% initiated systemic antihistamine use (n=1439) at visit 2 (*3*).

New Data Show MimyX Cream Helps Lengthen Remission Periods

Investigators recently conducted a multicenter, investigator-blind, bilateral 12-week study to determine the efficacy and safety of *MimyX Cream* plus a control applied twice daily as compared with control alone in reducing the risk of relapse of



AD (*4*). Participants had a history of bilateral AD, frequent flares, with 2% to 10% of the body surface area affected. Participants were in remission at study start and were not using any other topical medicated treatments, phototherapy, or systemic treatments. Participants in Group 1 applied *MimyX Cream* plus a control twice daily to all affected areas on the right side of the body, and Group 2, to the left side of the body. Both groups also applied the control alone twice daily to contralateral sides of the body. Investigators examined the participants at 2-week intervals to assess erythema, pruritus, and papulation/induration/edema, using a scale from 0 (absent) to 3 (severe).

MimyX Cream plus control resulted in a median time of 43 days until flare, versus 29 days for control alone (p=0.033, N=74), a 48% extended remission with *MimyX Cream*. In addition, more *MimyX Cream* plus control treated areas were without flare at study end (40.5% vs. 25.7%, p=0.051) (*4*).

MimyX Cream Is Well Liked and Well Tolerated

Study participants preferred *MimyX Cream* to control; 89% liked the product upon application, and 77% stated they would continue to use *MimyX Cream*. In addition, *MimyX Cream* has an excellent safety profile, with a low rate of adverse events (4.1% in this study). Three participants experienced an adverse event possibly related to *MimyX Cream* (burning, n=1; urticaria, n=1; and headache, n=1) and none of the adverse events were serious (*4*).

MimyX Cream is a steroid-free, foundational therapy that contains the lipids olea europaea, palm glycerides, hydrogenated lecithin, and squalane. It also contains palmitamide MEA (or PEA) (*5*), a naturally occurring essential fatty acid with proven anti-inflammatory properties (*4*). *MimyX Cream* is hypoallergenic, non-comedogenic and it can be used on the face. It also has no age or duration-of-use restrictions. *MimyX Cream* is indicated to manage and relieve the burning and itching experienced with various types of dermatoses, including atopic dermatitis, allergic contact dermatitis and radiation dermatitis. *MimyX Cream* is contraindicated in patients with known hypersensitivity to any of the components of the formulation. In radiation therapy, *MimyX Cream* may be applied as indicated by the treating Radiation Oncologist. Do not apply 4 hours prior to a radiation session. *MimyX Cream* does not contain a sunscreen and should not be used prior to extended exposure to the sun. It is for external use only. Prescribing information is available at: http://www.stiefel.com/products/inserts/Mimyx%20PI.pdf.

About Stiefel Laboratories, Inc.

Founded in 1847, Stiefel Laboratories is the world's largest independent pharmaceutical company specializing in dermatology. Its wholly-owned global network is comprised of more than 30 subsidiaries, including: manufacturing plants in six countries; R&D facilities on three continents; and products marketed in over 100 countries worldwide.

Stiefel supplements its R&D by aggressively seeking acquisitions of dermatological product lines and companies around the world.

Mimyx® cream

For more information concerning Stiefel Laboratories Inc., call 1-888-STIEFEL, or visit the company's web site at www.stiefel.com.

References:

1. Handout on Health: Atopic Dermatitis. National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health. Available at: http://www.niams.nih.gov/hi/topics/dermatitis/. Accessed January 4, 2006.
2. Carroll CL, Balkrishnan R, Feldman SR, Fleischer AB Jr, Manuel JC. The burden of atopic dermatitis: impact on the patient, family, and society. *Pediatr Dermatol*. 2005;22(3):192-99.
3. Eberlein-Koenig B, Eicke C, Reinhardt H-W, Ring J. Adjuvant treatment of subjects with atopic dermatitis: assessment of physiogel A.I. (MimyX Cream) (ATOPA). Abstract submitted for presentation at: 64th Annual Meeting of the American Academy of Dermatology; March 2006; San Francisco, CA.
4. Data on File. August C. Stiefel Research Institute, Inc.
5. MimyX Cream [package insert]. Coral Gables, FL: Stiefel Laboratories, Inc.; 2005