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EVOCLIN™ (CLINDAMYCIN PHOSPHATE) FOAM, 1%

Patient-Preferred VersaFoam® Formulation Now Available For the Treatment of Acne

Connetics Corporation (Palo Alto, CA), a specialty pharmaceutical company that develops and commercializes dermatology products, is pleased to announce the availability of **EVOCLIN**™, a once-daily topical Clindamycin foam indicated for the treatment of acne vulgaris. EVOCLIN received FDA approval on October 22, 2004, and is the first and only foam available for the treatment of acne. EVOCLIN distinguishes itself from other dermatological therapies with the use of Connetics' proprietary temperature-sensitive **VersaFoam**® vehicle, which has revolutionized topical drug delivery. EVOCLIN contains no bleaching agents and will not bleach or stain clothing or linens. EVOCLIN dissipates with body heat when applied to the skin and is suitable for all skin types and various body surface areas, including the face and hair-bearing or non-hair bearing areas. EVOCLIN is available in 50g and 100g trade unit sizes, as well as 10g professional samples. EVOCLIN should be applied once daily to the skin where acne lesions appear and enough should be used to sufficiently cover the entire affected areas.

EVOCLIN delivered in the VersaFoam brand vehicle sets itself apart from other applications due in large measure to its versatility to be used anywhere on the body where acne appears. The unique foam formulation dissolves rapidly at skin temperature, is easy to apply, is stain-free, drip-free, and leaves minimal to no residue. The 95º F melting temperature allows patients time to apply EVOCLIN to large body surface areas affected by acne. Additionally, in vitro studies demonstrate that the VersaFoam brand vehicle delivers active pharmaceutical ingredients across the outer skin membrane, depositing more medication into the skin as compared with two traditional topical delivery vehicles—cream and gel. Additionally, the VersaFoam brand contains no preservatives or fragrances. Responses from a survey of physicians and patients showed a clear preference for foam, which may provide for increased compliance compared to other dermatological vehicles, including lotions, gels, creams, and ointments (*1*).

Acne is the most common skin disorder in the United States, affecting at least 7

million people. More than 85% of individuals with acne are between the ages of 15 and 24. While many experience only a mild form of acne, 40% require treatment by a physician. Acne generally begins in adolescence when hormones (androgens) present in both males and females lead to increased oil secretion and inflammation. Skin cells clogging the skin's pores and *Propionibacterium acnes* also contribute to acne development. While most people outgrow acne by their early 20s, acne affects 8% of people 25-35 years of age, and some, especially women, can have acne into their 40s or 50s. Acne can be both emotionally and physically scarring. Topical preparations are often the sole treatment in many patients and are an element of the therapeutic regimen for almost all patients. Clindamycin, the active ingredient in EVOCLIN, is the most widely used topical antibiotic and has been prescribed for more than 20 years in the treatment and control of acne. Clindamycin is effective and well-tolerated, and with EVOCLIN*, is available for the first time in a foam vehicle (*2*). Clindamycin works by inhibiting the growth of *P. acnes*, the bacteria that produces acne, and by reducing inflammation.

The clinical data supporting FDA approval of EVOCLIN came from a randomized, double-blinded, multi-center trial of more than 1,000 patients age 12 and older. In the non-inferiority study the results indicated that EVOCLIN was a safe and effective treatment of acne and produced a reduction in total lesions by 43% (n=386) versus 36% (n=385) for the reference listed drug Clindamycin phosphate gel 1% and 31% (n=127) for vehicle foam ($p < 0.0001$ for EVOCLIN vs. vehicle foam). Adverse events were mild to moderate in nature; the most common adverse events reported were headache (3%) and application site reactions (burning (6%), itching (1%) and dryness (1%)). No allergic reactions were reported in this trial (*3*).

** EVOCLIN is contraindicated in individuals with a history of hypersensitivity to preparations containing clindamycin or lincomycin, or a history of regional enteritis, ulcerative colitis, or antibiotic-associated colitis. Diarrhea, bloody diarrhea, and pseudomembranous colitis have been reported with systemic and rarely with topical clindamycin. Discontinuation is recommended if diarrhea develops.*

For more information concerning Connetics Corporation or its products, call 1-888-969-CNCT, or visit the company's Web site at www.connetics.com or www.evoclin.com.

References:

1. In a post-study patient questionnaire, 73% of patients found the foam easier to use than other vehicles, 98% said they were more likely to comply with the foam treatment therapy and 66% found it superior to other vehicles when applying foam to any area of the body. In a survey of dermatologists, 91% responded that they believed the foam would enhance patient compliance.
2. Data on file, Connetics Corporation.
3. *Ibid.*

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