

GALDERMA ANNOUNCES POSITIVE RESULTS FROM THE “COMMPLETE” REGIMEN STUDY INCLUDING EPIDUO® GEL IN THE MANAGEMENT OF ACNE IN ADOLESCENT STUDENT ATHLETES

Young athletes need take extra precaution to safe guard their skin health, as 8 out of 10 of pre-teen and adolescent teens will encounter some form of acne as a natural side effect of puberty¹

Fort Worth, Texas, May 24, 2016 – Galderma Laboratories, L.P. today announced the results of the open-label single center study that evaluated the acne regimen comprised of Epiduo® (adapalene /benzoyl peroxide) Gel, 0.1%/2.5%, the #1 prescribed branded topical acne agent in the world,² which uses two antibiotic-free medicines for the treatment of acne, plus Cetaphil® DermaControl™ Face Wash and Cetaphil® DermaControl™ Moisturizer SPF 30 (referred to as the CoMMplete Regimen). It was shown that the CoMMplete Regimen was safe, effective and scored high in patient satisfaction for the treatment of acne vulgaris in adolescent student athletes.³ The data was presented at the 74th American Academy of Dermatology (AAD) annual meeting in Washington, D.C.

The eight (8) week study evaluated the effectiveness of the CoMMplete Regimen study on Texas University Interscholastic League (UIL) student athletes (N=28), ages 12-18, with mild to moderate acne. The results showed significantly reduced lesion counts compared to baseline (total, inflammatory, and noninflammatory lesions; P<.001) at week 8, a 29.6% mean change in total lesion count.³ Reduction in lesion counts were seen as early as week two in inflammatory lesions and total lesion counts, 11.1% and .05% respectively.³

Participants also reported good tolerability,³ minimal skin irritation³ and patient satisfaction³ when adhering to the acne regimen.

“The combination of Epiduo Gel, plus Cetaphil DermaControl Face Wash and Moisturizer with SPF 30 exhibited improvement,³” said Dr. Edward Lain, MD, MBA, lead study author and Galderma consultant. “This data has successfully shown the benefits of a skincare regimen to effectively treat acne vulgaris in young athletes.³”

Many teens and pre-teens will experience various degrees of acne due to the hormonal swells provoked by puberty.⁴ However, for adolescent athletes, skin irritants such as heat, moisture, friction and foreign cells,⁵ such as dirt and sweat, can obstruct the openings of microscopic exocrine glands, increasing the likelihood of frequent breakouts.¹ Athletic equipment, such as helmets, pads and tight clothing or uniforms, can often increase the occurrence of acne.⁵

Acne is the most common skin condition in the U.S., affecting 40-50 million Americans nationwide.¹ Epiduo Gel is the #1 prescribed branded topical acne agent in the world,² using two antibiotic-free medicines for the treatment of acne.⁶ For patients with mild to moderate acne, Epiduo Gel works to help treat current breakouts quickly and help prevent future pimples from forming.⁶

“At Galderma, we understand the impact acne has on various aspects of patients’ lives, especially among the pre-teen and teenage population,” said Miles Harrison, President and General Manager of Galderma Laboratories, L.P. “We are committed to science based skin health treatment options and helping patients manage and maintain skin health through an effective skin care regimen.”

About Acne

Acne is the most common skin condition in the United States, affecting more than 40 to 50 million people.¹ Acne appears when pores clog with dead skin cells,¹ and can have a wide-ranging negative impact on sufferers that includes both emotional and physical scars.⁷ Acne not only affects teenagers but also can be seen in men and women of all ages⁸ with research showing that the onset of acne is frequently seen in prepubescent patients.⁹

When it comes to acne treatment, long-term use of antibiotics may be a contributing factor to the overall global antibiotic resistance issue.¹⁰ *Propionibacterium acnes* (*P. acnes*), a bacteria linked to acne, is increasingly becoming resistant to topical and oral antibiotics,¹⁰ which may potentially cause a decrease in treatment efficacy against acne.¹⁰

About Galderma

Dating back to 1961, Galderma is now present in 100 countries with an extensive product portfolio to treat a range of dermatological conditions. The company partners with health care professionals around the world to meet the skin health needs of people throughout their lifetime. Galderma is a leader in

research and development of scientifically-defined and medically-proven treatment options for the skin, hair and nails.

Strategic brands in the U.S. include Epiduo® Gel, Epiduo® Forte Gel, Oracea® Capsules, Clobex® Spray, Differin® Gel, Mirvaso® Gel, MetroGel® Gel, Soolantra® Cream, Vectical® Cream, Tri-Luma® Cream, Cetaphil®, Benzac® Acne Solutions, Restylane®, Restylane® Silk, Restylane® Lyft, Dysport® (abobotulinumtoxinA) and Sculptra® Aesthetic.

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Important Safety Information

Indication: EPIDUO® Gel is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older. **Adverse Events:** In controlled clinical studies, the most commonly reported adverse events ($\geq 1\%$) in patients treated with EPIDUO® Gel were dry skin, contact dermatitis, application site burning, application site irritation and skin irritation. **Warnings/Precautions:** Patients taking EPIDUO® Gel should avoid exposure to sunlight and sunlamps and wear sunscreen when sun exposure cannot be avoided. Erythema, scaling, dryness, stinging/ burning, irritant and allergic contact dermatitis may occur with use of EPIDUO® Gel and may necessitate discontinuation.

Additional information on Epiduo Gel can be found in the prescribing information at www.epiduo.com.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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