

Galderma Receives FDA Approval for New Antibiotic-Free Treatment Option for Acne Patients

- FDA Approval of Epiduo® Forte (adapalene and benzoyl peroxide) Gel, 0.3%/2.5% Further Expands Galderma's Portfolio of Dermatologic Solutions -

FT. WORTH, Texas – July 16, 2015 - [Galderma Laboratories, L.P.](#) announced today that the U.S. Food and Drug Administration (FDA) approved antibiotic-free Epiduo® Forte (adapalene and benzoyl peroxide) Gel, 0.3%/2.5%, for the once-daily, topical treatment of acne vulgaris. Acne is the most common skin condition in the United States, affecting more than 40 to 50 million people. Epiduo Forte Gel is the first combination of these strengths of the retinoid, adapalene, and benzoyl peroxide, developed for the moderate to severe acne population.

"As the industry leader in dermatology, Galderma recognizes the need for innovative acne medications across a spectrum of acne severities," said Todd Zavodnick, President and General Manager of Galderma Laboratories, L.P. "The FDA approval of Epiduo Forte Gel has helped us expand on our robust acne franchise to deliver a safe, effective and antibiotic-free treatment to patients in need, and underscores Galderma's continued commitment to skin health and antibiotic stewardship."

The approval of Epiduo Forte Gel was based on a pivotal phase 3, multicenter, randomized, double-blind, 12-week, vehicle-controlled study in which it met each of its primary efficacy endpoints when compared to vehicle gel in 217 acne subjects. The study demonstrated superiority of Epiduo Forte Gel over vehicle gel in the overall study population (moderate to severe) at week 12 for the Investigator's Global Assessment Success Rate and for changes in inflammatory and non-inflammatory lesion count. Additionally, subjects who were "severe" at baseline (50%) were required to go from "severe" to "clear" or "almost clear" within the 12-week trial to be considered a treatment success. More than half of study subjects treated with Epiduo Forte Gel reported a marked improvement in their severe acne (50.5%).

"Acne is a challenging condition to manage. It can vary greatly from patient to patient, can have a significant physical and psychosocial impact on sufferers, and patients can find treatment adherence difficult to maintain," said Jonathan Weiss, MD, a board certified dermatologist at Gwinnett Dermatology, P.C. and leading clinical investigator for the phase 3 trial of Epiduo Forte Gel. "For many patients, rapid results are especially important, and some acne treatments take time to show effect. We

were very excited to see in the clinical trial that people using Epiduo Forte Gel saw results as early as one week, with efficacy continually improving through week 12.”

In the clinical trial, Epiduo Forte Gel was shown to be safe and well tolerated, and most adverse events (AEs) were mild to moderate in severity, which is important for acne patients with sensitive skin. The most commonly reported adverse events ($\geq 1\%$) in patients treated with Epiduo Forte Gel were skin irritation, eczema, atopic dermatitis and skin burning sensation. As an antibiotic-free acne treatment that was well tolerated in clinical trials, Epiduo Forte Gel can be considered for long-term use and offers convenience in a pump with once daily dosing. Epiduo Forte Gel will be available by prescription in early September 2015.

About Acne

Acne is the most common skin condition in the United States, affecting more than 40 to 50 million people. Acne appears when pores clog with dead skin cells, and can have a wide-ranging negative impact on sufferers that includes both emotional and physical scars. Studies show that many people who have acne suffer from low self-esteem and depression, and that teens who believe they have “bad” acne were likely to think about hurting themselves. Acne not only affects teenagers but also can be seen in men and women of all age with research showing that the onset of acne is frequently seen in prepubescent patients.

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

About Galderma

Dating back to 1961, Galderma is now present in 80 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 solutions for the skin, hair and nails.

Strategic brands in the U.S. include Epiduo® 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® and Sculptra® Aesthetic.

For more information, please visit www.galderma.com and www.galdermausa.com.

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Important Safety Information

Indication: Epiduo® Forte (adapalene and benzoyl peroxide) Gel, 0.3%/2.5% is indicated for the topical treatment of acne vulgaris. **Adverse Events:** In the pivotal study, the most commonly reported adverse reactions ($\geq 1\%$) in patients treated with Epiduo Forte Gel were skin irritation, eczema, atopic dermatitis and skin burning sensation. **Warnings/Precautions:** Patients using Epiduo Forte 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 Forte Gel and may necessitate discontinuation. When applying Epiduo Forte Gel, care should be taken to avoid the eyes, lips and mucous membranes.

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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