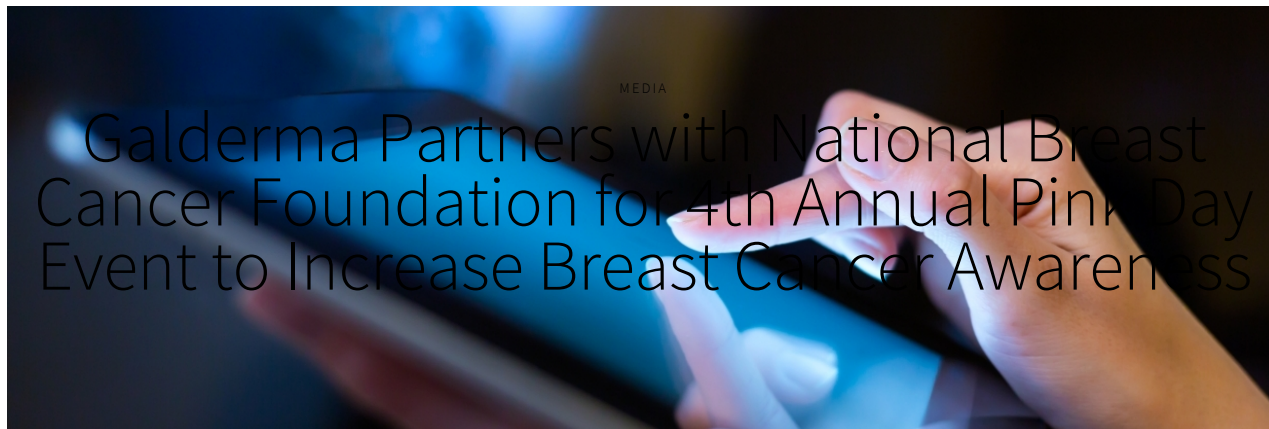


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## #1 Branded Topical Acne Product, Epiduo® GEL, Receives FDA Approval For a New Convenient Pump Dispenser

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December 15, 2011

### Study Shows that Acne Sufferers Prefer Pump Delivery for Treatment Administration

Fort Worth, Texas – December 15, 2011 – Galderma Laboratories, L.P. today received approval from the U.S. Food and Drug Administration (FDA) for a pump dispenser for Epiduo® (adapalene and benzoyl peroxide) Gel 0.1% / 2.5%. This approval marks the first-ever pump dispenser for Epiduo Gel, the only once-daily, topical acne treatment that combines two well-established active ingredients adapalene, a retinoid, and benzoyl peroxide, a well-known antimicrobial with no evidence of promoting bacterial resistance, for patients 12 years of age and older. Epiduo Gel is the #1 branded topical acne product among dermatologists and pediatricians.<sup>1</sup> The Epiduo Gel pump will be available via prescription in the first quarter of 2012 in pharmacies nationwide.

“Because acne is caused by a multitude of factors, management of the condition has traditionally relied on combination therapy,” said Dr. Linda Stein Gold, Director, Dermatology Clinical Research, Henry Ford Health System, Detroit, and Division Head, Dermatology, Henry Ford Health System, West Bloomfield. “As a dermatologist I often prescribe Epiduo Gel, which combines two effective medications into one product to treat both inflammatory and non-inflammatory lesions topically. My patients have often achieved very positive results, and I believe that patients will be excited about the new pump delivery system for its convenience and administration benefits.”

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Studies indicate that Epiduo Gel is more efficacious than either of its components used alone, and has had no evidence of promoting antibiotic resistance. Epiduo Gel simplifies the management of acne and significantly reduces total acne lesions by approximately 18 percent as early as the first week of treatment. Epiduo Gel also helps to reduce the complexity of acne management by reducing the number of medications a patient has to remember to take on a daily basis, potentially increasing treatment adherence.

In a recently completed preference survey, 92 percent of patients were satisfied or very satisfied with the new pump for Epiduo Gel.<sup>2a</sup> The survey, which ascertained patient preference for the Epiduo Gel pump vs. the tube, involved 291 physician-diagnosed acne patients, ages 12 to 35.<sup>2b, 2c</sup> The randomized study found that with use of the Epiduo Gel pump, patients found it to be more convenient, easier to use and more attractive than the tube.<sup>2d</sup> Of note, the study concluded that:

- Nearly 80 percent of patients said they would request the pump over the tube the next time they visit their doctor.<sup>2e</sup>
- 88 percent of patients said the Epiduo Gel pump made it easier for them to follow their doctor's instructions.<sup>2f</sup>
- More than 90 percent of patients found the Epiduo Gel pump to deliver a consistent amount of the gel to their face during each use, and also to save time during treatment administration.<sup>2g</sup>
- 93 percent of patients said the Epiduo Gel pump was more attractive than the tube; in fact, 84 percent of patients said they were more likely to leave the Epiduo Gel pump out on the counter.<sup>2h</sup>

### **About Acne**

Acne vulgaris is one of the most widely experienced chronic skin diseases. In recent years, research has led to a greater understanding of the pathogenesis of the disease.<sup>3</sup> The disorder begins with the onset of puberty and is thought to result from hormonal action on the skin's oil glands (sebaceous glands) leading to plugged pores and outbreaks.<sup>4</sup> It can be challenging to manage due to the variability in response to treatment and the need for long term therapy.<sup>5</sup>

### **About Galderma**

Galderma, created in 1981 as a joint venture between Nestle and L'Oréal, is a fully-integrated specialty pharmaceutical company dedicated exclusively to the field of dermatology. The Company has a presence in 65 countries with over 1,000 sales representatives and is committed to improving the health of skin with an extensive line of products across the world that treat a range of dermatological conditions including: acne, rosacea, fungal nail infections, psoriasis and steroid-responsive dermatoses, pigmentary disorders, medical solutions for skin senescence and skin cancers. With a research and development center in Sophia Antipolis, France. Galderma has one of the

largest R&D facilities dedicated exclusively to dermatology. Leading U.S. brands include Epiduo® Gel, Differin® Gel, 0.3%, Differin® Lotion, 0.1%, MetroGel® 1%, Oracea®, Cetaphil®, Tri-Luma® Cream, and Vectical® Ointment.

For more information about Galderma, please visit [www.galderma.com](http://www.galderma.com) (<https://www.galderma.com/us/www.galderma.com>).

### **Important Safety Information**

Epiduo® Gel is indicated for the topical treatment of acne vulgaris in patients 12 years and older. Apply to affected skin once per day, avoiding the eyes, lips and mucous membranes. The most common adverse events associated with use of Epiduo® Gel are redness, scaling, dryness, stinging and burning. In addition, you may also experience contact dermatitis and/or skin irritation. These side effects typically resolve during the first four weeks of treatment, but speak to your doctor if they persist. You should avoid excessive exposure to sunlight and sunlamps while using Epiduo® Gel, and using sunscreen products and protective clothing is recommended. Do not use irritating topical products that contain resorcinol, salicylic acid or sulfur when using Epiduo® Gel. Epiduo® Gel has not been tested in pregnant or nursing women, or with the elderly. Please see Full Prescribing Information.

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

### **References:**

<sup>1</sup> Galderma Data on File.

<sup>2</sup> Galderma Laboratories, L.P. Clinical Study Report (Gli.04.Sre.Us10184). August 2011.

<sup>3</sup> Gollnick H, Cunliffe WJ, Berson D et al. Management of Acne: A Report From a Global Alliance to Improve Outcomes in Acne. *J Am Acad Dermatol.* 2003; 49(1):S1-S37.

<sup>4</sup> Nemours Foundation. Why Do I Get Acne? [http://www.kidshealth.org/teen/your\\_body/skin\\_stuff/acne.html](http://www.kidshealth.org/teen/your_body/skin_stuff/acne.html).

<sup>5</sup> Thiboutot D, Pariser DM, Egan N et al. Adapalene gel 0.3% for the treatment of acne vulgaris: A multicenter, randomized, double-blind, controlled trial. *J Am Acad Dermatol.* 2006; 54:242-50.



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