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Galderma Announces FDA Approval of Full Prescription-Strength Differin® Gel For Over-the-Counter Acne Use

First new active ingredient approved to treat acne without a prescription in over 30 years

Fort Worth, TX (July 8, 2016) – Galderma, a global leader focused on medical solutions in skin health, today announced that its U.S. affiliate, Galderma Laboratories, L.P. received approval from the U.S. Food and Drug Administration (FDA) for Differin® Gel (adapalene gel 0.1%) as an over-the-counter (OTC) treatment for acne. This approval makes Differin® Gel the first and only OTC acne product containing a full prescription-strength retinoid. It also marks the first new, FDA-approved active ingredient to be introduced to the OTC acne category in over three decades.

“We believe bringing Differin® Gel over-the-counter will be a game-changer for consumers and for the acne category,” said Miles Harrison, President and General Manager of Galderma Laboratories, L.P. “We’re excited to deliver this new level of efficacy without a prescription to consumers, and to bring the first new active ingredient to the category in over 30 years. As the research and development leader of medically proven dermatologic solutions, Galderma is proud to announce this innovation will be available for people with skin health needs.”

Acne is the most common skin condition in the United States, affecting up to 60 million teens and adults annuallyⁱ, however, only one-third seek out the help of a healthcare provider to address these issues². In fact, 45 percent of adults are not satisfied with their current productsⁱⁱⁱ, with nearly half of people using three or more acne productsⁱⁱ. With a growing trend among consumers to self-treat, many turn to the skincare aisle at their local drugstore. Until now, there have been only two active ingredients on the over-the-counter market*, leaving many people dissatisfied and searching for better options. With the Rx to OTC switch of Differin® Gel, millions of people will have easier access to a full prescription-strength product containing a retinoid.

"This landmark approval was years in the making at Galderma and demonstrates our ongoing commitment to individuals with dermatologic concerns such as acne," said Philip Brown, MD, JD, Senior Vice President, Medical and Regulatory Affairs, Galderma Laboratories, L.P. "Galderma will continue to partner with healthcare professionals and invest in Rx, OTC and Aesthetic & Corrective medical innovations to enhance skin health."

About Differin® Gel

Differin® Gel containing 0.1% adapalene is specially formulated for efficacy and tolerability. It is a full prescription-strength, once-a-day topical containing a retinoid, which is clinically proven to treat current and future breakouts. An innovation from Galderma R&D, the dermatologist-developed and tested Differin® Gel contains adapalene, a safe and effective retinoid, which doctors have prescribed to over 40 million people globally for more than 20 years^{iv}. According to the American Academy of Dermatology's therapeutic treatment guidelines, topical retinoids are recommended as first-line therapy for all acne cases^v.

Differin® Gel is clear, fragrance-free, oil-free and alcohol-free. Differin® Gel is applied once daily, directly to the full-face or other affected areas. It is approved for use by people 12 years and older with acne.

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

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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, 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.

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

Contact

Virginie Naigeon, Director of Corporate Communications, North America
Galderma Laboratories, L.P.
14501 N Fwy Service Rd E
Fort Worth, TX 76177
virginie.naigeon@galderma.com

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ⁱ Bickers DR, Lim HW, Margolis D, Weinstock MA, Goodman C, Faulkner E and others. The burden of skin diseases: 2004: A joint project of the American Academy of Dermatology Association and the Society for Investigative Dermatology. *Journal of the American Academy of Dermatology*, Vol. 55, Issue 3, p490-500 Published in issue September 2006. DOI: <http://dx.doi.org/10.1016/j.jaad.2006.05.048>

ⁱⁱ Data on File. Liebman 2009

ⁱⁱⁱ Nielsen Bases 1 2015

^{iv} Data on file, Galderma Laboratories, L.P.

^v "Treatment and management of acne." American Academy of Dermatology. AAD.org, 6 May 2016. Web. 26 June 2016.

* Disclaimer: There are five (5) approved active ingredients, but only two that make up 99% of the market.