

Galderma Announces Availability of Soolantra® (ivermectin) Cream, 1%

Newly Approved Prescription Treatment Option Now Available for Rosacea Patients in Pharmacies Nationwide

FT. WORTH, Texas--(BUSINESS WIRE)--Galderma Laboratories, L.P. today announced that Soolantra® (ivermectin) Cream, 1% – a once-daily, antibiotic-free, prescription topical treatment for rosacea – is now approved by the FDA and available in pharmacies in the United States. In clinical studies of patients with inflammatory lesions, or bumps and pimples, of rosacea, Soolantra Cream effects were seen, as early as week two, with continuous improvement with long-term use.

Although the cause of rosacea is unknown, research suggests that there are multiple triggers for the inflammation associated with the condition, including sun, alcohol, spicy food and exercise. Recent studies have further solidified that microscopic, generally harmless Demodex mites may also be a culprit. These mites are normal inhabitants of everyone’s skin, but may appear in greater number on the faces of people with rosacea. While the mechanism of action of Soolantra Cream is unknown, ivermectin, the active ingredient in Soolantra Cream, has been reported to have both anti-inflammatory and antiparasitic activity.

“The availability of Soolantra Cream as a treatment for inflammatory lesions of rosacea offers a novel option to consider for my patients,” said Linda Stein Gold, M.D., Galderma consultant and clinical investigator for the phase 3 studies of Soolantra Cream. “Rosacea patients now have a powerful yet safe option that may work as fast as two weeks.”

The approval of Soolantra Cream was based on data collected from more than 1300 patients with moderate to severe inflammatory lesions of rosacea enrolled in two phase 3 clinical studies of a 12-week duration. Furthermore, in a separate head to head study with metronidazole 0.75% cream – a current gold standard – Soolantra Cream was shown to be more efficacious as early as week three. In long-term extension studies, Soolantra Cream was safe and well-tolerated for up to 52 weeks, which is critical as rosacea patients have sensitive skin. Some study subjects experienced skin burning sensation and skin irritation while using Soolantra Cream.

“At Galderma, we recognize the frustration that rosacea symptoms can bring and as a result, we’ve been working with the rosacea community to drive awareness and to bring solutions to patients for decades,” said Stuart Raetzman, Chief Executive Officer of Galderma Laboratories, L.P. and Senior Vice President, North America. “We are constantly innovating to address gaps in current care and with the addition of Soolantra Cream, patients and physicians have a new, unique option to consider.”

About Rosacea

Rosacea is a common, inflammatory disorder affecting the face. Redness, visible blood vessels, bumps, and pimples typically appear in the middle of the face (forehead, nose, cheeks) after age 30 in men and women.

Because of the physical manifestation of rosacea on the face, the condition can cause embarrassment, anxiety and frustration, and can have a negative impact on the patient’s social life. Stinging, burning and sensitivity of the skin are common, and in some cases, the eyes can become red, dry and itchy. Triggers

for the condition may include spicy foods, alcohol, emotional stress, sun exposure, hot baths and generally harmless, microscopic Demodex mites found on the skin.

If left untreated, rosacea may worsen. If people suspect that they might have rosacea, they should visit their dermatologist or healthcare provider for diagnosis and to discuss what treatment is right for them.

About Galderma - A global company exclusively dedicated to dermatology

Galderma is a global company founded in 1981 committed to delivering innovative medical solutions to meet the dermatological needs of people throughout their lifetime while serving healthcare professionals around the world. The company has 34 wholly-owned affiliates with a worldwide network of distributors and more than 5,000 employees. Galderma's extensive product portfolio is available in 80 countries and treats a range of dermatological conditions including: acne, rosacea, onychomycosis, psoriasis & steroid-responsive dermatoses, pigmentary disorders, skin cancer and medical solutions for skin senescence.

With approximately 19 percent of revenues invested each year to discover and develop new products and access innovative technologies, the company is one of the world's leading investors in dermatology R&D. Five state-of-the-art R&D centers and five manufacturing sites are dedicated to providing a wide range of innovative medical solutions which meet the highest standards of safety and efficacy. Strategic brands in the U.S. include Cetaphil®, Epiduo®, Oracea®, Mirvaso®, Clobex®, Differin®, MetroGel®, Vectical®, Tri-Luma®, Pliaglis® and Benzac®.

All trademarks are the property of their respective owners.

For more information, please visit: GaldermaUSA.com

Important Safety Information - Soolantra® Cream

Indication: SOOLANTRA® (ivermectin) Cream, 1%, is indicated for the treatment of inflammatory lesions of rosacea. **Adverse Events:** In clinical trials with SOOLANTRA® Cream, the most common adverse reactions (incidence ≤ 1 %) included skin burning sensation and skin irritation. **Warnings / Precautions:** Not for oral, ophthalmic or intravaginal use

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