About Soolantra® (ivermectin) Cream, 1%

What is Soolantra Cream?

- Soolantra® (ivermectin) Cream, 1% is approved by the FDA for the once-daily, topical treatment of inflammatory lesions, or bumps and pimples, of rosacea. The FDA approval of Soolantra Cream addresses an important need of patients with bumps and pimples – a common symptom of rosacea, a frustrating, and embarrassing condition.

How Does Soolantra Cream Work?

- 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 approval of Soolantra Cream was based on two pivotal phase 3, multicenter, randomized, double-blind, 12-week, vehicle-controlled, parallel-group studies in which it met each of its co-primary efficacy endpoints. The onset of treatment effect was observed as early as week two with continuous improvement.
- 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.
- Some study subjects experienced skin burning sensation and skin irritation while using Soolantra Cream.

What is Rosacea?

- Rosacea is a common, inflammatory and vascular disorder affecting the face, characterized by redness, visible blood vessels, bumps and pimples.
- A variety of emotional and environmental triggers can cause the condition to flare unpredictably, resulting in lower self-confidence and self-esteem.
- 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 also highlighted the role of microscopic, generally harmless Demodex mites, as another potential trigger. These mites are normal inhabitants of everyone’s skin, but may appear in greater numbers on the faces of people with rosacea.
How Does the Condition Manifest for Patients?

- Rosacea symptoms manifest differently for individual patients, so treatment must be tailored to fit what works for the individual. For many rosacea sufferers, symptoms appear as bumps and/or pimples, the hallmarks of the inflammatory lesions of rosacea, which Soolantra Cream is approved to treat.
- If left untreated, rosacea may worsen, so anyone who suspects they have rosacea should visit their dermatologist or healthcare provider for diagnosis and treatment.

A phase 3, multicenter, randomized, double-blind, 12-week, vehicle-controlled, parallel-group study assessing the efficacy and safety of Soolantra® (ivermectin) Cream, 1% QD in 688 subjects with moderate to severe inflammatory lesions of rosacea (Investigator Global Assessment [IGA] score of 3 or 4).

Soolantra® is a trademark of Galderma S.A.

For more information, visit www.Soolantra.com or consult your dermatologist.

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