Galderma Launches EPSOLAY® Cream, a Medical Advance to Treat Bumps and Blemishes of Rosacea

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FDA-approved EPSOLAY (benzoyl peroxide) Cream, 5% is now available by prescription across the U.S.

FORT WORTH, Texas, June 2, 2022 /PRNewswire/ -- Galderma announced today the availability of EPSOLAY (benzoyl peroxide) Cream, 5% in the U.S. following approval by the U.S. Food and Drug Administration (FDA) on April 22, 2022. EPSOLAY Cream is the first and only microencapsulated benzoyl peroxide (E-BPO) topical treatment proven to relieve the bumps and blemishes of rosacea and provides rapid, significant and sustained relief.[1,2] [a]

To view the Multimedia News Release, please click:
https://www.multivu.com/players/uk/9055151-galderma-launches-epsolay-cream/

Over 16 million people in the U.S. struggle with rosacea, a chronic and recurrent skin condition that can worsen over time.[3] More than 82% of people feel their rosacea is uncontrolled, and less than 50% are satisfied with their current prescription treatments, which can lead to overuse or misuse of these products and can trigger or worsen the condition.[4-7] Rosacea can be so challenging to manage that 55% of people with the skin condition and a high disease burden, reported a willingness to give up one year or more of their life to cure their symptoms.[8]

"Through our decades-long heritage in dermatology and skin science, Galderma is committed to bringing cutting-edge innovation to patients with rosacea and the healthcare professionals who treat them," said Anthony Pansy, Vice President and General Manager of the U.S. prescription business at Galderma. "EPSOLAY Cream represents an important advancement for those who are living with this incredibly challenging skin condition."

In clinical trials, treatment with EPSOLAY Cream reduced bumps and blemishes of rosacea by up to 43.7% in two weeks[b] and by nearly 70% in 12 weeks.[9] Unlike ordinary BPO which can be irritating, EPSOLAY Cream gradually releases benzoyl peroxide onto the skin, making it suitable and well-tolerated for the sensitive skin of rosacea patients. In a 52 week long-term safety study, side effects which occurred in participants using EPSOLAY Cream were mostly mild in nature.[11] In 12 week trials, almost 50% of participants who used EPSOLAY Cream in the trial were clear or almost clear by 12 weeks.[9,10] [c] The most common adverse reactions (incidence ≥ 1%) in participants treated with EPSOLAY Cream were pain, erythema (redness), pruritus (itching) and edema (swelling), occurring all at the application site.[2]

"Until now, BPO has never been indicated to treat rosacea in part due to its poor tolerability for sensitive skin. EPSOLAY Cream helps overcome tolerability issues via its patented microencapsulation technology which controls the gradual release of BPO onto the skin," said Ted Lain, MD, Executive Director, Austin Institute for Clinical Research and principal investigator for the EPSOLAY Cream clinical trials. "EPSOLAY Cream showed great efficacy and tolerability in the pivotal trials, as evidenced by high patient satisfaction and compliance."

A month's supply of EPSOLAY Cream costs as little as $0 for commercially covered patients with the Galderma CAREConnect savings card at participating pharmacies.

a. As found in participants treated with EPSOLAY In clinical trials over 12 weeks
b. Multiple imputation was used to input missing values. Percent at Week 2 represents average values obtained from averaging the summary statistics imputed from each imputed data set
c. As demonstrated in 2 phase 3 clinical trials (trials showed 50.1% and 43.5% of subjects were 'clear' or 'almost clear' at 12 weeks)

About EPSOLAY®

EPSOLAY is a topical cream containing benzoyl peroxide (BPO), 5%, for the treatment of bumps and blemishes (inflammatory lesions) of rosacea in adults.[2] EPSOLAY utilizes a proprietary, patented technology licensed from Sol-Gel Technologies (Nasdaq: SLGL) to encapsulate BPO within silica-based microcapsules to create a barrier between the medication and the skin.[12] The silica-based shell is designed to slowly release BPO over time to provide a tolerable and effective treatment.[1,11]

Sol-Gel Technologies received FDA approval for EPSOLAY Cream on April 22, 2022 and has granted exclusive rights to Galderma to commercialize the treatment in the U.S.

For additional information, please visit www.epsolay.com

About Galderma

Galderma is the world's largest independent dermatology company, present in approximately 100 countries. Since our inception in 1981, we have been driven by a complete dedication to dermatology. We deliver an innovative, science-based portfolio of sophisticated brands and services across Aesthetics, Consumer Care and Prescription Medicine. Focused on the needs of consumers and patients, we work in partnership with healthcare professionals to ensure superior outcomes. Because we understand that the skin we're in shapes our life stories, we are advancing dermatology for every skin story.

For additional information, please visit www.galderma.com/us

Media Relations

Zach Randles-Friedman
Head, Corporate Communications, U.S., R&D and Corporate Development

zach.randles-friedman@galderma.com
+1 305-299-5700

Shannon Iwaniuk
Director, U.S. Communications
shannon.iwaniuk@galderma.com
+1 720 308 1336

IMPORTANT SAFETY INFORMATION

Indication: EPSOLAY® (benzoyl peroxide) Cream, 5% is indicated for the treatment of inflammatory lesions of rosacea in adults. **Adverse Events:** The most common adverse reactions (incidence ≥ 1%) in patients treated with EPSOLAY Cream were pain, erythema (redness), pruritus (itching) and edema (swelling), all at the application site. **Warnings/Precautions:** Patients using EPSOLAY Cream may experience hypersensitivity reactions, including anaphylaxis (acute allergic reaction), angioedema (rapid swelling), and urticaria (hives). If serious hypersensitivity reaction occurs, discontinue use of EPSOLAY Cream immediately and seek medical attention/initiate appropriate therapy. Skin Irritation/contact dermatitis may be experienced, including erythema (redness), scaling, dryness, and stinging/burning. Irritation and contact dermatitis may occur. Use a moisturizer and discontinue EPSOLAY Cream if symptoms do not improve. Avoid application to cuts, abrasions, eczematous, or sunburned skin. EPSOLAY Cream may increase photosensitivity, sensitivity to ultraviolet light. Minimize or avoid exposure to natural or artificial sunlight (tanning beds or UVA/B treatment). Use sunscreen or protective clothing when sun exposure cannot be avoided. Discontinue use of EPSOLAY Cream at the first evidence of sunburn.

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

See full prescribing information for EPSOLAY here.

References

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