

Epsolay[®] (benzoyl peroxide) – New drug approval

- On April 25, 2022, [Sol-Gel Technologies announced](#) the FDA approval of [Epsolay \(benzoyl peroxide\)](#) 5% cream, for the treatment of inflammatory lesions of rosacea in adults.
- The benzoyl peroxide in Epsolay is uniquely designed within silica-based microcapsules to slowly release benzoyl peroxide over time.
- The efficacy and safety of Epsolay was evaluated in two identical Phase 3 randomized, double-blind, vehicle-controlled clinical trials in 733 adult patients with moderate to severe papulopustular rosacea. In both trials, patients were treated once daily for 12 weeks with either Epsolay or vehicle cream for both trials. The co-primary endpoints in both trials were the proportion of patients with Investigator Global Assessment (IGA) treatment success at Week 12 and the absolute change from baseline in inflammatory lesion counts at Week 12.
 - In Trial 1:
 - IGA treatment success was achieved in 47.4% of patients with Epsolay vs. 20.7% in patients with vehicle cream (treatment difference 26.7, 95% CI: 16.7, 36.8).
 - The mean percent change in inflammatory lesions was -68.2% in patients who received Epsolay vs. -38.3% in those who received vehicle cream (treatment difference -29.9, 95% CI: -37.8, -22.0).
 - In Trial 2:
 - IGA treatment success was achieved in 49.2% of patients with Epsolay vs. 28.2% in patients with vehicle cream (treatment difference 21.0, 95% CI: 10.7, 31.3).
 - The mean percent change in inflammatory lesions was -69.4% in patients who received Epsolay vs. -46.0% in those who received vehicle cream (treatment difference -23.4, 95% CI: -30.5, -16.3).
- Warnings and precautions for Epsolay include hypersensitivity reactions, skin irritation/contact dermatitis, and photosensitivity.
- The most common adverse reactions ($\geq 1\%$) with Epsolay use were application site reactions: pain, erythema, pruritis, and edema.
- Epsolay is applied as a pea-sized amount once daily in a thin layer to each area of the face (forehead, chin, nose, each cheek) on clean and dry skin.
- Sol-Gel Technologies has partnered with Galderma to commercialize Epsolay in the U.S. but launch plans are still pending. Epsolay will be available as a cream in a 50-gram airless pump.