



Twyneo® (tretinoin/benzoyl peroxide) – New drug approval

- On July 27, 2021, [Sol-Gel Technologies](#) announced the [FDA approval](#) of [Twyneo \(tretinoin/benzoyl peroxide\)](#), for the topical treatment of acne vulgaris in adults and pediatric patients 9 years of age and older.
- The efficacy of Twyneo was established in two identical, randomized, double-blind, vehicle-controlled studies in 858 patients 9 years of age and older with facial acne vulgaris. The co-primary endpoints were the absolute change from baseline in non-inflammatory lesion count, and absolute change in inflammatory lesion count at week 12 and the proportion of patients with Investigator Global Assessment (IGA) success at week 12, defined as an IGA score of 0 (“clear”) or 1 (“almost clear”), and at least a two-grade improvement (decrease) from baseline at week 12.
 - In study 1, IGA success was achieved in 39.9% of patients treated with Twyneo vs. 14.3% with placebo (difference: 25.7, 95% CI: 17.1, 34.2). In study 2, IGA success was achieved in 26.8% of patients treated with Twyneo vs. 15.1% with placebo (difference: 11.6; 95% CI: 3.6, 19.7).
 - In study 1, the mean percent change from baseline in inflammatory lesions was -66.1% and -43.5% for Twyneo and placebo, respectively (difference: -22.6, 95% CI: -29.2, -16.0). In study 2, the mean percent change from baseline in inflammatory lesions was -57.6% and -50.8%, respectively (difference: -6.8, 95% CI: -13.1, -0.5).
 - In study 1, the mean percent change from baseline in non-inflammatory lesions was -61.6% and -40.9% for Twyneo and placebo, respectively (difference: -20.7, 95% CI: -27.2, -14.2). In study 2, the mean percent change from baseline in non-inflammatory lesions was -54.4% and -41.5%, respectively (difference -13.0, 95% CI: -19.6, -6.4).
- Warnings and precautions for Twyneo include hypersensitivity, skin irritation, and photosensitivity.
- The most common adverse reactions ($\geq 1\%$) with Twyneo use were pain, dryness, exfoliation, erythema, dermatitis, pruritus, and irritation (all at the application site).
- The recommended dose of Twyneo is an application of a thin layer to the affected areas once daily on clean and dry skin.
 - Contact should be avoided with the eyes, lips, paranasal creases, and mucous membranes.
- Sol-Gen’s launch plans for Twyneo are pending. Twyneo will be available as a 0.1% tretinoin/3% benzoyl peroxide cream.



OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at [optum.com](#).

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2021 Optum, Inc. All rights reserved.