

Cabtreo™ (clindamycin phosphate/adapalene/benzoyl peroxide) – New drug approval

- On October 20, 2023, [Bausch Health announced](#) the FDA approval of [Cabtreo \(clindamycin phosphate/adapalene/benzoyl peroxide\)](#), for the topical treatment of acne vulgaris in adult and pediatric patients 12 years of age and older.
- Cabtreo is the first fixed-dose, triple combination topical treatment for acne.
- The efficacy of Cabtreo was established in two, randomized, double-blind studies in 363 adult and pediatric patients 10 years of age and older with facial acne vulgaris. While patients aged 10 to less than 12 years were included in these trials, Cabtreo is not approved for use in patients less than 12 years of age. Patients were randomized to receive Cabtreo or vehicle applied once daily for 12 weeks. The co-primary endpoints were success on the Evaluator's Global Severity Score (EGSS), absolute change in noninflammatory lesion count, and absolute change in inflammatory lesion count at week 12.

Trial 1	Cabtreo	Vehicle	Treatment difference (95% CI)
EGSS success	49.6%	24.9%	24.7 (10.7, 38.7)
Non-inflammatory facial lesions			
Mean absolute reduction	35.4	23.5	11.9 (7.1, 16.6)
Mean percent reduction	72.7%	47.6%	--
Inflammatory facial lesions			
Mean absolute reduction	27.7	21.7	5.9 (3.1, 8.7)
Mean percent reduction	75.7%	59.6%	--
Trial 2	Cabtreo	Vehicle	Treatment difference (95% CI)
EGSS success	50.5%	20.5%	30.0 (16.4, 43.6)
Non-inflammatory facial lesions			
Mean absolute reduction	35.2	22.0	13.3 (8.8, 17.7)
Mean percent reduction	73.3%	49.0%	--
Inflammatory facial lesions			
Mean absolute reduction	30.1	20.8	9.3 (6.2, 12.4)
Mean percent reduction	80.1%	56.2%	--

- Cabtreo is contraindicated in patients with:
 - Known hypersensitivity to clindamycin, adapalene, benzoyl peroxide, any other components of Cabtreo, or lincomycin
 - A history of regional enteritis, ulcerative colitis, or antibiotic-associated colitis.
- Warnings and precautions for Cabtreo include hypersensitivity, colitis, photosensitivity, and skin irritation and allergic contact dermatitis.
- The most common adverse reactions (> 1% of the Cabtreo group and greater than the vehicle group) with Cabtreo use were application site reactions, pain, erythema, dryness, irritation, exfoliation, and dermatitis.

- Cabtreo is applied as a thin layer to the affected area once daily.
- Bausch plans to launch Cabtreo in first quarter of 2024. Cabtreo will be available as a 1.2% clindamycin phosphate, 0.15% adapalene, and 3.1% benzoyl peroxide topical gel (20-gram and 50-gram pumps).



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