



Aklief[®] (trifarotene) – New drug approval

- On October 4, 2019, the FDA approved Galderma Laboratories' [Aklief \(trifarotene\)](#) cream, for the topical treatment of acne vulgaris in patients 9 years of age and older.
- Aklief is an agonist of retinoic acid receptors.
- The efficacy of Aklief was established in two identical, double-blind studies in 2,420 patients with moderate facial and truncal acne vulgaris. Patients were randomized to Aklief or a vehicle-control. The co-primary endpoints (evaluated on the face) were the percentage of patients achieving success on the Investigator's Global Assessment (IGA) scale, the mean absolute change in facial inflammatory lesion count from baseline, and the mean absolute change in facial non-inflammatory lesion count from baseline, all evaluated at week 12.
 - In study 1, facial IGA success was achieved in 29.4% and 19.5% of patients receiving Aklief and vehicle, respectively. The mean absolute change in facial inflammatory lesion count from baseline was -19.0 (-54.4%) vs. -15.4 (-44.8%). The mean absolute change in facial non-inflammatory lesion count from baseline was -25.0 (-49.7%) vs. -17.9 (-35.7%).
 - In study 2, facial IGA success was achieved in 42.3% and 25.7% of patients receiving Aklief and vehicle, respectively. The mean absolute change in facial inflammatory lesion count from baseline was -24.2 (-66.2%) vs. -18.7 (-51.2%). The mean absolute change in facial non-inflammatory lesion count from baseline was -30.1 (-57.7%) vs. -21.6 (-43.9%).
- Warnings and precautions for Aklief include skin irritation and ultraviolet light and environmental exposure.
- The most common adverse reactions ($\geq 1\%$) with Aklief use were application site irritation, application site pruritus, and sunburn.
- The recommended dosing of Aklief is a thin layer application to the affected areas once daily, in the evening, on clean and dry skin.
 - One pump actuation should be enough to cover the face (ie, forehead, cheeks, nose, and chin).
 - Two actuations of the pump should be enough to cover the upper trunk (ie, reachable upper back, shoulders and chest). One additional pump actuation may be used for middle and lower back if acne is present.
- Galderma's launch plans for Aklief are pending. Aklief will be available as a 0.005% cream.



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