# *EPIDUO® FORTE* (ADAPALENE AND BENZOYL PEROXIDE) GEL, 0.3%/2.5% REDUCES ACNE LESIONS AND THE RISK OF ACNE SCARRING

In the pivotal study*, EPIDUO FORTE Gel demonstrated nearly twice the efficacy of vehicle in the reduction of inflammatory lesions with rapid reduction at week 1; significant clearing at week 12. Mean scores for erythema, dryness, scaling and stinging/burning peaked at Week 1, decreased thereafter, and were mild to moderate in severity. The most commonly reported adverse reactions (>1%) in patients treated with EPIDUO FORTE Gel were skin irritation, eczema, atopic dermatitis and skin burning sensation.

## The OSCAR Study

Two-phase, randomized, multicenter, investigator-blinded, vehicle-controlled trial evaluating once-daily EPIDUO® FORTE (adapalene and benzoyl peroxide) Gel 0.3%/2.5% in male or female subjects 16 to 35 years old with a clinical diagnosis of moderate to severe acne vulgaris on the face (defined by IGA score of 3 or 4, with the same score on both sides); a minimum of 25 inflammatory lesions (papules and pustules) in total, with at least 10 on each side (excluding the nose); no more than 2 acne nodules ≥1 cm; and 10 or more atrophic acne scars in total >2 mm, excluding the nose. Phase 1 was a split-face, 24- week, investigator-blinded, vehicle-controlled evaluation (N=67) at 8 visits (baseline, weeks 1, 4, 8, 12, 16, 20, and 24). Phase 2 was a whole-face, open-label observation with 2 visits. Primary endpoint was scar count at Week 24.

## The Results:

**22%** GREATER DECREASE of total lesions (-73% vs. -51%) than vehicle at 24 weeks[1]

**29%** GREATER DECREASE of inflammatory lesions (-87% vs. -58%) than vehicle at 24 weeks[1]

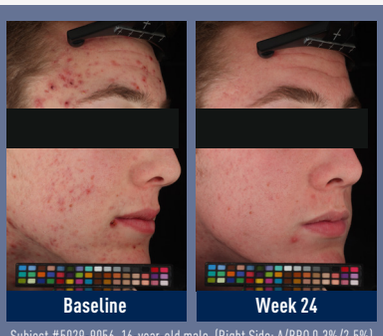
**18%** GREATER DECREASE of non-inflammatory lesions (-60% vs. -41%) than vehicle at 24 weeks[1]

Failure to treat acne with EPIDUO FORTE Gel **increased the risk of scarring**[2]

- This superiority is statistically supported by the success rate of Investigator's Global Assessment (IGA) of acne, with a difference of **45%** in Clear/Almost Clear subjects at week 24 (**64%** vs. 19%).[2]
- **Continuous improvement** in subjects' acne was observed until week 24 with treatment of EPIDUO FORTE Gel.[1]
- Most common treatment-related adverse events (AEs) were mild to moderate skin irritation (reported by 15% of subjects treated with EPIDUO FORTE Gel and 6% of subjects treated with vehicle).[1]
- EPIDUO FORTE Gel was **safe and well tolerated**.[1,3]

After 24 weeks of treatment, **90%** of subjects stated they were satisfied to very satisfied with EPIDUO FORTE Gel vs. **59%** of those treated with vehicle.[2]

Almost **84%** of subjects would consider using EPIDUO FORTE Gel again vs. 57% with vehicle.[2]




Subject #5029-9056. 16-year-old male. (Right Side: A/BPO 0.3%/2.5%) Clinical Study RD.03.SPR.105061. Galderma R&D.

**EPIDUO FORTE Gel reduces acne lesions and the risk of scarring for results your patients can see.[2]**

## Important Safety Information

**Indication:** EPIDUO® FORTE (adapalene and benzoyl peroxide) Gel, 0.3%/2.5% is indicated for the topical treatment of acne vulgaris. **Adverse Events:** In the pivotal study, the most commonly reported adverse reactions (≥1%) in patients treated with EPIDUO FORTE Gel were skin irritation, eczema, atopic dermatitis and skin burning sensation. **Warnings/Precautions:** Patients using EPIDUO FORTE Gel should avoid exposure to sunlight and sunlamps and wear sunscreen when sun exposure cannot be avoided. Erythema, scaling, dryness, stinging/burning, irritant and allergic contact dermatitis may occur with use of EPIDUO FORTE Gel and may necessitate discontinuation. When applying EPIDUO FORTE Gel, care should be taken to avoid the eyes, lips and mucous membranes.

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.

Please see accompanying full prescribing information including patient information for more details.

## *Pivotal Study

A multicenter, randomized, double-blind, parallel-group, active- and vehicle-controlled, 12-week study comparing the efficacy and safety of once-daily adapalene 0.3%/BPO 2.5% fixed-dose combination gel (n=217) relative to vehicle (n=69) in subjects with moderate to severe acne vulgaris. At baseline, subjects had between 20 and 100 inflammatory lesions and 30 to 150 noninflammatory lesions. A once-daily adapalene 0.1 %/BPO 2.5% ann was included as a safety comparator (n=217); the study was not powered to compare efficacy with adapalene 0.3%/BPO 2.5%.

## References

[1] Data on File: RD.03.SPR.105061, September 2017. [2] Data on File: RD.03.SPR.105061, August 24, 2017.[3] Data on File: RD.03.SPR.105061, September 22, 2017.


Galderma Laboratories, L.P. 14501 N Freeway, Fort Worth, TX 76177

USMP/EFO/0022/0118(1)