

About Epiduo[®] Forte (adapalene and benzoyl peroxide) Gel, 0.3%/2.5%

What is Epiduo Forte Gel?

- Epiduo Forte (adapalene and benzoyl peroxide) Gel, 0.3%/2.5% is approved by the FDA for the once-daily, topical treatment of acne vulgaris.
- Epiduo Forte Gel is the first combination of these strengths of the retinoid, adapalene, and benzoyl peroxide, developed for the moderate to severe acne population.
 - Epiduo Forte Gel contains the highest concentration of adapalene, which works to unclog blocked pores and inhibits the release of proinflammatory mediators, helping to stop acne from forming under the skin's surface and decreasing the redness, swelling and inflammation associated with pimples.
 - The concentration of benzoyl peroxide in Epiduo Forte Gel is a well-established antimicrobial that kills bacteria that lead to breakouts and helps prevent pimples from coming back.
- As an antibiotic-free acne treatment that was well tolerated in clinical trials, Epiduo Forte Gel can be considered for long-term use and offers convenience in a pump with once daily dosing.

How Did Epiduo Forte Gel Work in Clinical Trials?

- The approval of Epiduo Forte Gel was based on a pivotal phase 3, multicenter, randomized, double-blind, 12-week, vehicle-controlled study in which it met each of its primary efficacy endpoints when compared to vehicle gel in 217 acne subjects. Subjects who were “severe” at baseline (50%) were required to go from “severe” to “clear” or “almost clear” within the 12-week trial to be considered a treatment success.
- Subjects including those with severe acne continued to improve over the 12-week study.
- The study demonstrated superiority of Epiduo Forte Gel over vehicle gel in the overall study population at week 12 based on the Investigator’s Global Assessment Success Rate. In addition, changes were observed in inflammatory and non-inflammatory lesion counts.
- In the clinical trial, Epiduo Forte Gel was shown to be safe and well tolerated, and most adverse events (AEs) were mild to moderate in severity, which is important for acne patients with sensitive skin.
- The most commonly reported adverse events ($\geq 1\%$) in patients treated with Epiduo Forte Gel were skin irritation, eczema, atopic dermatitis and skin burning sensation.

What is Acne?

- Acne is the most common skin condition in the United States, affecting more than 40 to 50 million people.
- Acne appears when pores clog with dead skin cells, and can have a wide-ranging negative impact on sufferers that includes both emotional, such as low self-esteem and depression, and physical scars.
- When it comes to acne treatment, long-term use of antibiotics may contribute to the problem of antibiotic resistance, increasing resistance to treatment of the bacteria linked to acne and other bacterial diseases.

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 trial, the most commonly reported adverse reactions ($\geq 1\%$) 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.

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