

Zilxi™ (minocycline) – New drug approval

- On May 29, 2020, [Menlo Therapeutics announced](#) the FDA approval of [Zilxi \(minocycline\)](#) topical foam, for the treatment of inflammatory lesions of rosacea in adults.
 - This formulation of minocycline has not been evaluated in the treatment of infections. To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, Zilxi should be used only as indicated.
- Topical minocycline is also available as a 4% topical foam ([Amzeeq™](#)) for the treatment of moderate to severe acne vulgaris.
- Rosacea is a diverse skin condition that most commonly presents with symptoms such as deep facial redness, spider veins and acne-like inflammatory lesions.
 - Rosacea is most frequently seen in adults between 30 and 50 years of age. It affects more than 16 million people in the U.S.; up to 28% of these sufferers have rosacea with inflammatory lesions.
- The safety and efficacy of Zilxi was assessed in two 12-week, double-blind, vehicle-controlled studies in 1,522 patients with inflammatory lesions of rosacea. The co-primary efficacy endpoints were the absolute change from baseline in inflammatory lesion counts at week 12 and the proportion of patients with treatment success at week 12, defined as an Investigator Global Assessment (IGA) score of 0 (“clear”) or 1 (“almost clear”), and at least a two-grade improvement (decrease) from baseline at week 12.
 - In the first study, IGA treatment success was seen in 52.1% of Zilxi-treated patients vs. 43.0% of vehicle-treated patients (treatment difference: 9.0%; 95% CI: 1.3, 16.8). The mean absolute change in lesion counts was -17.6 in Zilxi-treated patients and -15.4 in vehicle-treated patients (treatment difference: -2.2; 95% CI: -3.7, -0.7).
 - In the second study, IGA treatment success was seen in 49.1% of Zilxi-treated patients vs. 39.0% of vehicle-treated patients (treatment difference: 10.2%; 95% CI: 3.1, 17.4). The mean absolute change in lesion counts was -18.4 in Zilxi-treated patients and -14.5 in vehicle-treated patients (treatment difference: -3.9; 95% CI: -5.5, -2.2).
- Warnings and precautions for Zilxi include flammability, teratogenic effects, tooth discoloration, inhibition of bone growth, *Clostridioides difficile* associated diarrhea, hepatotoxicity, metabolic effects, central nervous system effects, intracranial hypertension, autoimmune syndromes, photosensitivity, serious skin/hypersensitivity reaction, tissue hyperpigmentation, development of drug-resistant bacteria, and superinfection/potential for microbial overgrowth.
- The most common adverse effect ($\geq 1\%$) with Zilxi use was diarrhea.
- Zilxi should be applied to affected areas once daily. After the can is shaken well, a small amount of topical foam (eg, a cherry-sized amount) should be expressed from the can onto the fingertips of the hand and then applied as a thin layer over all areas of the face. Additional Zilxi foam may be used as needed to ensure the entire face is treated.

- Menlo Therapeutics plans to launch Zilxi in the fourth quarter of 2020. Zilxi will be available as an 1.5% topical foam



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