

## Amzeeq™ (minocycline) – New drug approval

- On October 18, 2019, [Foamix Pharmaceuticals](#) announced the FDA approval of [Amzeeq \(minocycline\)](#) topical foam, for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in adults and pediatric patients 9 years of age and older.
  - 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, Amzeeq should be used only as indicated.
- Amzeeq, a tetracycline-class drug, is the first FDA approved topical minocycline formulation. Minocycline is currently available as an oral tablet and capsule.
- The efficacy of Amzeeq was established in three 12-week, randomized, double-blind, vehicle-controlled studies in 2,418 patients with moderate to severe acne vulgaris. 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 score of 0 (“clear”) or 1 (“almost clear”), and at least a two-grade improvement (decrease) from baseline at week 12.

|  | Study 1                                 |         | Study 2                               |         | Study 3                                  |         |
|--|---|---------|---------------------------------------|---------|--|---------|
|  | Amzeeq                                  | Vehicle | Amzeeq                                | Vehicle | Amzeeq                                   | Vehicle |
| Treatment success  | 8.1%                                    | 4.8%    | 15.8%                                 | 8.4%    | 30.8%                                    | 19.6%   |
|  | Difference: 3.3%<br>(95% CI: -1.5, 8.2) |         | Difference: 7.4%<br>(95% CI: 0, 13.7) |         | Difference: 11.2%<br>(95% CI: 6.6, 15.8) |         |
| Inflammatory lesion count<br>(mean % change from baseline) | -44%                                    | -34%    | -43%                                  | -34%    | -54%                                     | -42%    |
|  | Difference: -10%<br>(95% CI: -17, -3)   |         | Difference: -10%<br>(95% CI: -17, -2) |         | Difference: -12%<br>(95% CI: -16, -8)    |         |

- Warnings and precautions for Amzeeq include flammability, teratogenic effects, tooth discoloration, inhibition of bone growth, *Clostridium 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, superinfection/potential for microbial overgrowth.
- The most common adverse reaction with Amzeeq use was headache.
- Amzeeq should be applied to affected areas once daily.
  - 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 rubbed into acne-affected parts of the face.
  - This should be repeated as needed until all acne-affected parts of the face are treated. If acne is present on other parts of the patient’s body (neck, shoulders, arms, back or chest), additional amounts of topical foam should also be applied to these areas.

- Foamix Pharmaceuticals plans to launch Amzeeq in January 2020. Amzeeq will be available as a 4% topical foam.



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