Amzeeq (minocycline foam)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Amzeeq
- **Generic name:** Minocycline (as HCl)
- **Pharmacologic class:** Tetracycline antibiotic
- **Strength and Formulation:** 4%; foam; contains alcohol
- **Manufacturer:** Foamix
- **How supplied:** Foam—30g
- **Legal Classification:** Rx

Amzeeq


NDC 72356-101-03
amzeeq™
(minocycline)
topical foam, 4%
For topical use only,
not for oral, ophthalmic
or intravaginal use
Rx only
foamix®
Pharmaceuticals
30 g

Indication

- Topical treatment of inflammatory lesions of non-nodular moderate to severe **acne vulgaris** in adults and pediatric patients 9 years of age and older

Limitations of Use

- This formulation of minocycline has not been evaluated in the treatment of infections

Dosage and Administration

- <9yrs: **not established**
- **≥9yrs**: apply at the same time each day ≥1 hour before bedtime
- Rub gently into affected area(s); repeat as needed
- Avoid bathing, showering or swimming for ≥1 hour after application
- Propellant in product is flammable

Considerations for Special Populations

- **Pregnancy:** systemic absorption low following once daily topical administration for 21 days; not expected that maternal use will result in significant fetal exposure to the drug
- **Nursing mothers**: breastfeeding *not recommended* during treatment
- **Pediatric**: safety and effectiveness have not been established in pediatric patients less than 9 years of age
- **Geriatric:** studies did not include sufficient number of patients ≥65 years

Warnings/Precautions

- Not for oral, ophthalmic, or intravaginal use
- Monitor blood, renal, and hepatic function periodically
- Monitor for visual disturbances
- History of intracranial hypertension
- Overweight women
- Avoid sunlight or UV light; discontinue at 1st sign of sunburn
- Discontinue if serious skin reactions (eg, Stevens Johnson syndrome, erythema multiforme, DRESS syndrome) or superinfection develop

Interactions

- **Avoid** concomitant penicillins, isotretinoin
- May need to reduce concomitant anticoagulant dose
- May interfere with fluorescence test

Adverse Reactions

- **Most common**: headache
- **Others** (associated with *oral minocycline*): teeth discoloration, delayed skeletal development, intracranial hypertension, CNS effects, *C.difficile*-associated diarrhea, increased BUN, hepatotoxicity, renal toxicity, photosensitivity, skin/hypersensitivity reactions (may be severe), hyperpigmentation, autoimmune syndromes (eg, lupus-like syndrome, serum sickness; discontinue if symptoms occur)

Mechanism of Action

- Minocycline hydrochloride is a semi-synthetic derivative of tetracycline
- Tetracyclines are primarily bacteriostatic and are thought to exert their antimicrobial effect by the inhibition of protein synthesis
- Each gram of Amzeeq contains 40mg of minocycline equivalent to 43mg of minocycline HCl
- The mechanism of action for the treatment of acne is unknown

Clinical Trials

- Amzeeq was assessed in three 12-week, multicenter, randomized, double-blind, vehicle-controlled studies in patients with moderate to severe acne vulgaris
- Efficacy was assessed in a total of 2418 patients 9 years of age and older
- Amzeeq or its vehicle were applied once daily for 12 weeks; no other topical or systemic medication affecting the course of acne vulgaris was permitted for use during these studies

Clinical Trials

- Patients were required to have an inflammatory and noninflammatory lesion count in the range of 20-50 lesions and 25-100 lesions respectively, and an Investigator Global Assessment (IGA) score of 3 (“moderate”) or 4 (“severe”) at baseline
- At baseline, patients had a mean inflammatory lesion count of 31.2 and a mean noninflammatory lesion count of 49.3
- Approximately 85% had an IGA score of 3

Clinical Trials

- The co-primary efficacy end points 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 IGA score of 0 (“clear”) or 1 (“almost clear”), and at least a 2-grade improvement (decrease) from baseline at Week 12

Clinical Trials

- **Study 1**
  - IGA (treatment success): 8.1% for Amzeeq vs 4.8% for vehicle
  - Mean absolute change from baseline in inflammatory lesion count: -14.0 for Amzeeq vs -11.2 for vehicle
- **Study 2**
  - IGA: 15.8% for Amzeeq vs 8.4% for vehicle
  - Mean absolute change from baseline in inflammatory lesion count: -13.7 for Amzeeq vs -10.5 for vehicle
- **Study 3**
  - IGA: 30.8% for Amzeeq vs 19.6% for vehicle
  - Mean absolute change from baseline in inflammatory lesion count: -16.4 for Amzeeq vs -12.7 for vehicle

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/drug/amzeeq/