Zilxi (minocycline topical foam)

NEW PRODUCT SLIDESHOW

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Introduction

- **Brand name:** Zilxi
- **Generic name:** Minocycline (as HCl)
- **Pharmacologic class:** Tetracycline antibiotic
- **Strength and Formulation:** 1.5%; topical foam; contains alcohol
- **Manufacturer:** Vyne Therapeutics
- **How supplied:** Foam—30g
- **Legal Classification:** Rx

Zilxi


NDC 72356-103-03
zilxi™
(minocycline)
topical foam, 1.5%
For topical use only,
not for oral, ophthalmic
or intravaginal use
Rx only
30 g

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Indication

- Treatment of inflammatory lesions of **rosacea** in adults.

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Limitations of Use

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

Dosage and Administration

- For topical use only; not for oral, ophthalmic, or intravaginal use.
- Apply at the same time each day at least 1 hour before bedtime.
- Apply a thin layer onto affected area(s) of the face; additional foam may be used as needed to ensure the entire face is treated.
- Avoid bathing, showering or swimming for at least 1 hour after application.

Considerations for Specific Populations

- **Pregnancy:** Insufficient data to evaluate a drug-associated risk.
- **Nursing mothers:** Not recommended while breastfeeding.
- **Pediatric**: Not established.
- **Geriatrics**: No overall differences between the elderly and younger patients.

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Contraindications

- Hypersensitivity to any of the tetracyclines or any other ingredients in Zilxi.

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Warnings and Precautions

- Monitor for visual disturbances prior to initiation.
- Increased risk of intracranial hypertension in women of childbearing age who are overweight or have a history of intracranial hypertension.
- 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.
- Hepatic or renal impairment.
- Product is flammable.

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Interactions

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

Adverse Reactions

- **Most common (≥ 1%)**: Diarrhea.
- **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).

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Mechanism of Action

- The mechanism of action of **Zilxi** for the treatment of inflammatory lesions of rosacea is unknown.

Clinical Trials

- Approval was based on two 12-week multicenter, randomized, double-blind, vehicle-controlled trials (Trial 1 and Trial 2) that assessed the efficacy and safety of Zilxi in 1522 patients aged 18 years and older with inflammatory lesions of rosacea.
- Patients were randomized 2:1 to receive either Zilxi once daily or vehicle for 12 weeks.
- No other topical or systemic medication affecting the course of inflammatory lesions of rosacea was permitted for use during the trials.

Clinical Trials

- **Patient demographics**
  - Patients were required to have an inflammatory lesion count in the range 15-75 lesions 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 29.4 and approximately 87% of patients had an IGA score of 3.
  - Age: 25% (n=380) were 18 to 40 years of age; 59% (n=899) were 41 to 64 years of age; 16% (n=240) were 65 years or older.
  - 96% White; 71% female.

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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

- **Trial 1**
  - Mean absolute change from baseline in inflammatory lesion count: -17.6 for Zilxi vs -15.4 for vehicle.
  - Mean percent change from baseline in inflammatory lesion count: -61.3% for Zilxi vs -54.1% for vehicle.
  - IGA Success: 52.1% for Zilxi vs 43.0% for vehicle.
- **Trial 2**
  - Mean absolute change from baseline in inflammatory lesion count: -18.4 for Zilxi vs -14.5 for vehicle.
  - Mean percent change from baseline in inflammatory lesion count: -60.2% for Zilxi vs -48.9% for vehicle.
  - IGA Success: 49.1% for Zilxi vs 39.0% for vehicle.

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New Product Monograph

- For more information view the product monograph available at:

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