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

(minocycline)
topical foam, 1.5%

For topical use only, not for oral, ophthalmic or intravaginal use

Fix only

30 g
Indication

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

- Hypersensitivity to any of the tetracyclines or any other ingredients in Zilxi.
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.
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).
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.
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.
New Product Monograph

- For more information view the product monograph available at:
  
  https://www.empr.com/drug/zilxi/