Seysara (sarecycline)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Seysara
- **Generic name:** Sarecycline
- **Pharmacological class:** Tetracycline antibiotic
- **Strength and Formulation:** 60mg, 100mg, 150mg; tabs
- **Manufacturer:** Almirall, LLC
- **How supplied:** Tabs—30
- **Legal Classification:** Rx

Indication

- Non-nodular moderate-to-severe **acne vulgaris**

- **Limitations of use:**
  - Efficacy beyond 12 weeks and safety beyond 12 months: not established
  - Not evaluated in treating infections

Dosage & Administration

- Take with fluids
- **≥9yrs:**
  - 33–54kg: 60mg once daily
  - 55–84kg: 100mg once daily
  - 85–136kg: 150mg once daily
- Re-evaluate if no improvement after 12 weeks

Considerations for Special Populations

- **Pregnancy:** Teratogenic effects; during 2nd & 3rd trimester: may cause permanent discoloration of the teeth or reversible inhibition of bone growth
- **Nursing mothers:** Not recommended
- **Pediatric:** <9yrs: not recommended
- **Elderly:** Insufficient number studied

Warnings/Precautions

- **Discontinue** if superinfection develops
- History of intracranial hypertension
- Monitor for visual disturbances
- Overweight women
- Evaluate if diarrhea occurs; **discontinue** if *C. difficile*-associated diarrhea is suspected or confirmed
- **Avoid** sun or UV light

Interactions

- **Avoid** concomitant penicillins, oral retinoids
- May need to reduce concomitant anticoagulant dose
- **Separate** dosing from antacids containing aluminum, calcium, magnesium, bismuth subsalicylate, and iron-containing products
- Concomitant **P-gp substrates** (eg, digoxin); monitor for toxicity and reduce dose as needed

Adverse Reactions

- Nausea
- Tooth discoloration
- Enamel hypoplasia
- Inhibition of bone growth (up to 8yrs of age)
- *C.difficile*-associated diarrhea
- Intracranial hypertension
- Photosensitivity
- CNS effects
- Male infertility

Mechanism of Action

- Seysara is a narrow-spectrum tetracycline-derived antibiotic
- Its mechanism of action in treating acne vulgaris is not known

Pharmacokinetics

- **Metabolism:** Hepatic: minimal (<15%) *in vitro*
- **Elimination:** Fecal (42.6%); Renal (44.1%)

Clinical Studies

- The efficacy and safety of Seysara was assessed in two 12-week multicenter, randomized, double-blind, placebo-controlled studies (**Study 1** and **Study 2**) involving 2002 patients aged 9 years and older

Clinical Studies

- **Co-primary efficacy endpoints:**
  - Percentage of subjects with Investigator's Global Assessment (IGA) success: a score of **clear** (0) or **almost clear** (1) and 2-point decrease from baseline on IGA score at Week 12
  - Absolute reduction from baseline in inflammatory lesion counts at Week 12

Clinical Studies

- In **Study 1**, IGA success was observed in **21.9%** of patients in the Seysara arm vs **10.5%** of patients in the placebo arm

- In **Study 2**, IGA success was observed in **22.6%** of patients in the Seysara arm vs **15.3%** of patients in the placebo arm

Clinical Studies

- **Mean absolute** and **percent reduction** in inflammatory lesions was also greater with Seysara vs placebo at Weeks 3, 6, and 9 for both studies

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/seysara/drug/34909/