

## [New Drug Approvals](#)

### Generic Name (Trade Name—Company)

October 2, 2018

### Sarecycline

(*Seysara—Almiral*)

**New oral antibiotic targets moderate to severe acne**

### Uses/Notes

[Amirall announced](#) FDA approval of sarecycline, an innovative first-in-class tetracycline-derived oral antibiotic for treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients aged 9 years and older.

Sarecycline is an oral tablet that is taken once daily with or without food. It has proven to significantly reduce inflammatory lesions as early as 3 weeks after start of treatment and is generally safe and well tolerated.

Safety of the product was established in two 12-week multicenter, randomized, double-blind, placebo-controlled studies. Efficacy was assessed in 2,002 participants aged 9 years and older. Efficacy of sarecycline beyond 12 weeks and safety beyond 12 months have not been established.

Sarecycline has not been evaluated for treatment of infections. To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, patients should use sarecycline only as indicated. The product is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines.

Use during tooth development may cause permanent discoloration of the teeth. If *Clostridium difficile*-associated diarrhea (antibiotic-associated colitis) or intracranial hypertension occurs, use should be discontinued. Central nervous system adverse effects, including light-headedness, dizziness, or vertigo, have been reported with tetracycline use. The most common adverse reaction is nausea.

Sarecycline is expected to be launched in January 2019.

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