

## Seysara™ (sarecycline) – New drug approval

- On October 2, 2018, [Paratek Pharmaceuticals](#) and [Almirall](#) announced the [FDA approval](#) of [Seysara \(sarecycline\)](#), for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older.
  - Efficacy of Seysara beyond 12 weeks and safety beyond 12 months have not been established. Seysara has not been evaluated in the treatment of infections.
  - To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, Seysara should be used only as indicated.
- Acne vulgaris is a common chronic skin disease involving blockage and/or inflammation of hair follicles and their accompanying sebaceous gland. Acne can present as non-inflammatory lesions, inflammatory lesions, or a mixture of both, affecting mostly the face but also the back and chest.
  - Acne vulgaris affects 80% of Americans at some time during their lives. Of those affected, 20% have severe acne, which can result in permanent physical and mental scarring.
- Seysara is a tetracycline-derived antibiotic. The exact mechanism of action of Seysara in treating acne is not known.
- The safety and efficacy of Seysara were assessed in two 12-week studies comparing Seysara vs. placebo. Efficacy was assessed in a total of 2,002 patients ≥ 9 years of age. The two co-primary endpoints were: (1) percentage of patients with Investigator's Global Assessment (IGA) success and (2) absolute reduction from baseline in inflammatory lesion counts.
  - In study 1, IGA success for Seysara and placebo was 21.9% and 10.5%, respectively; the mean absolute reduction from baseline in inflammatory lesions was 15.3 and 10.2, respectively.
  - In study 2, IGA success for Seysara and placebo was 22.6% and 15.3%, respectively; the mean absolute reduction from baseline in inflammatory lesions was 15.5 and 11.1, respectively.
- Warnings and precautions of Seysara include teratogenic effects, *Clostridium difficile* associated diarrhea, central nervous system effects, intracranial hypertension, photosensitivity, development of drug-resistant bacteria, and superinfection/potential for microbial overgrowth.
- The most common adverse reaction (≥ 1%) with Seysara use was nausea.
- The recommended dose of Seysara is weight-based, once daily, with or without food. If there is no improvement after 12 weeks, treatment with Seysara should be reassessed.

Body Weight	Tablet Strength
33 to 54 kg	60 mg
55 to 84 kg	100 mg
85 to 136 kg	150 mg

- Almirall plans to launch Seysara in January 2019. Seysara will be available as 60 mg, 100 mg, and 150 mg tablets.



OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at [optum.com](https://www.optum.com).

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2018 Optum, Inc. All rights reserved.