

(<http://blog.pharmacist.com>)

[Home](#) > FDA approves once-daily I.V. and oral antibiotic for treatment of CABP and ABSSSI

Generic Name:

Omadacycline

Trade Name:

Nuzyra

Company:

Paratek

Notes:

[Paratek announced](#) FDA approval of omadacycline 100 mg for injection/150 mg tablets for treatment of community-acquired bacterial pneumonia (CABP) and acute skin and skin structure infections (ABSSSI) in adults.

Omadacycline, a modernized tetracycline, is a once-daily I.V. and oral antibiotic that targets a spectrum of bacteria, including Gram-positive, Gram-negative, atypicals, and drug-resistant strains.

Approval was supported by multiple clinical trials involving nearly 2,000 adult patients.

Warnings and precautions include the following:

Use during tooth development (last half of pregnancy, infancy, and childhood to age 8) may cause permanent discoloration of the teeth (yellow-gray-brown) and enamel hypoplasia.

Use during the second and third trimester of pregnancy, infancy and childhood up to age 8 years may cause reversible inhibition of bone growth.

Omadacycline is structurally similar to other tetracycline-class antibacterial drugs and is contraindicated in patients with known hypersensitivity to tetracycline-class antibacterial drugs.

Clostridium difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis.

The most common adverse reactions (incidence $\geq 2\%$) in clinical trials were nausea, vomiting, infusion-site reactions, alanine aminotransferase increased, aspartate aminotransferase increased, gamma-glutamyl transferase increased, hypertension, headache, diarrhea, insomnia, and constipation.

The drug is expected to become available in the first quarter of 2019.

Medication Monitor Categories:

[New Drug Approvals](#)

Source URL: <http://blog.pharmacist.com/new-drug-approvals/fda-approves-once-daily-iv-and-oral-antibiotic-treatment-cabp-and-absssi>