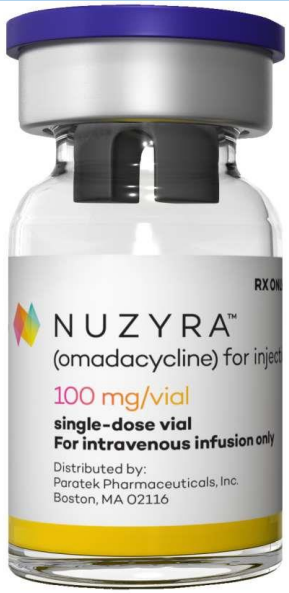
Nuzyra (omadacycline)



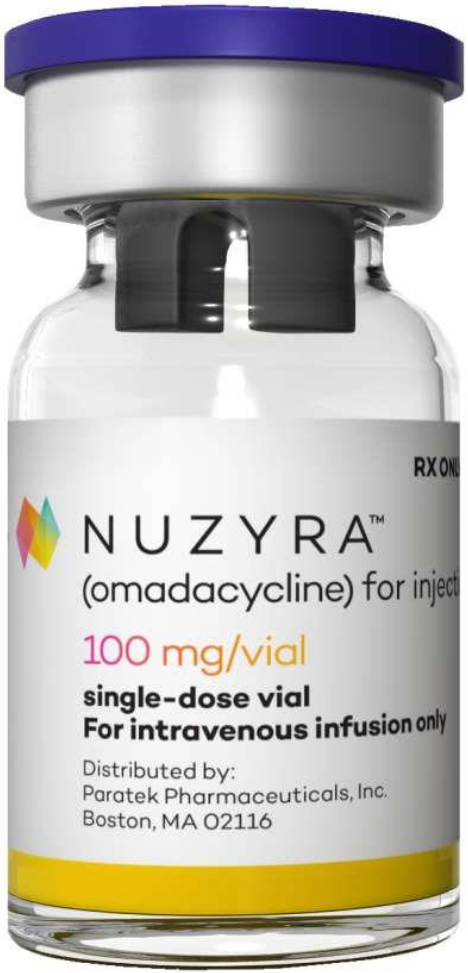
NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Nuzyra
- **Generic name:** Omadacycline
- **Pharmacological class:** Tetraycycline antibiotic
- **Strength and Formulation:** 150mg tabs; 100mg per vial lyophilized pwd for IV infusion
- **Manufacturer:** Paratek Pharmaceuticals
- **How supplied:** Tabs—30; Single-dose vials —10
- **Legal Classification:** Rx

Nuzyra


NUZYRA™
(omadacycline) for inject
100 mg/vial
single-dose vial
For intravenous infusion only
Distributed by:
Paratek Pharmaceuticals, Inc.
Boston, MA 02116


OMC
150

Indications

- **Community-acquired bacterial pneumonia** (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydophila pneumoniae*
- **Acute bacterial skin and skin structure infections** (ABSSSI) caused by the following susceptible microorganisms: *S. aureus* (methicillin-susceptible and -resistant isolates), *Staphylococcus lugdunensis*, *Streptococcus pyogenes*, *Streptococcus anginosus* grp. (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *Enterococcus faecalis*, *Enterobacter cloacae*, and *K. pneumoniae*

Dosage & Administration

- Tabs: Fast for ≥4hrs and take with water
- Treatment duration: 7–14 days
- **CABP:**
  - Day 1: Initially 200mg IV over 60mins or 100mg IV over 30mins twice
  - Maintenance: 100mg IV over 30mins once daily or 300mg orally once daily

Dosage & Administration

- **ABSSSI:**
  - Day 1: Initially 200mg IV over 60mins or 100mg IV over 30mins twice
  - Maintenance: 100mg IV over 30mins once daily or 300mg orally once daily

or

- Tabs only:
  - Day 1 and Day 2: 450mg orally once daily
  - Maintenance: 300mg orally once daily

Considerations for Special Populations

- **Pediatric:** <8yrs: not recommended (see full labeling); <18yrs: not established
- **Pregnancy:** during 2nd& 3rd trimester): may cause permanent discoloration of the teeth or reversible inhibition of bone growth
- **Nursing mothers:** not recommended (during and for 4 days after the last dose)
- **Elderly:** No significant difference in exposure

Warnings/Precautions

- **Mortality imbalance** in CABP; closely monitor response esp. those at higher risk (eg, >65yrs, comorbidities)
- **Discontinue** if allergic reaction occurs
- Evaluate if **diarrhea** occurs; discontinue if *C. difficile*-associated diarrhea is suspected or confirmed
- Advise females of reproductive potential to use effective contraception during treatment

Interactions

- May need to reduce concomitant anticoagulant dose
- **Inj:** do not give with multivalent cation-containing solutions (eg, Ca, Mg, Al) through same IV line
- **Tabs:** after dosing, avoid food or drink (except water) for 2hrs; and avoid dairy, antacids, iron preparations, multivitamins for 4hrs

Adverse Reactions

- Nausea
- Vomiting
- Infusion site reactions
- AST/ALT/GGT increase
- Hypertension
- Headache
- Diarrhea
- Insomnia
- Constipation
- Hypersensitivity reactions
- Tooth discoloration
- Enamel hypoplasia
- Inhibition of bone growth (up to 8yrs of age)

Adverse Reactions

- *C. difficile*-associated diarrhea
- Tetracycline class effects (eg, photosensitivity, pseudotumor cerebri, increased BUN, azotemia, acidosis, hyperphosphatemia, pancreatitis)

Mechanism of Action

- Omadacycline is an aminomethylcycline antibacterial within the tetracycline class of antibacterial drugs
- Omadacycline binds to the 30S ribosomal subunit and blocks protein synthesis
- It is active *in vitro* against Gram positive bacteria expressing tetracycline resistance active efflux pumps and ribosomal protection proteins

Clinical Studies

- **Trial 1** (N=774) was a randomized, multinational, double-blind, double-dummy trial that compared Nuzyra to moxifloxacin in adults with CABP
- Total treatment duration was 7 to 14 days; all patients were expected to require a minimum of at least 3 days of IV treatment

Clinical Studies

- Clinical success at the early clinical response (ECR) timepoint (72 to 120 hours after 1st dose) was defined as survival with improvement in at least 2 of 4 symptoms (cough, sputum production, chest pain, dyspnea) without deterioration in any of these 4 symptoms in the intent-to-treat population

Clinical Studies

- Clinical success at ECR timepoint was seen in **81.1%** of Nuzyra-treated patients vs **82.7%** of moxifloxacin-treated patients (difference -1.6, 95% CI, -7.1, 3.8)
- Clinical success at the post-therapy evaluation visit (PTE), 5 to 10 days after last dose, was seen in **87.6%** of Nuzyra-treated patients vs **85.1%** of moxifloxacin-treated patients (difference 2.5, 95% CI, -2.4, 7.4)

Clinical Studies

- **Trial 2** and **Trial 3** (N=1390) were randomized, multicenter, multinational, double-blind, double-dummy trials that compared 7 to 14 days of Nuzyra to linezolid in adults with ABSSSI
- Enrolled patients had cellulitis, major abscess or wounded infection

Clinical Studies

- In both trials, **efficacy** was determined by successful early clinical response at 48 to 72 hours after the first dose in the modified ITT population (defined as 20% or greater decrease in lesion size)

Clinical Studies

- In **Trial 2**, clinical success at ECR timepoint was seen in **84.8%** of Nuzyra-treated patients vs **85.5%** of linezolid-treated patients (difference -0.7, 95% CI, -6.3, 4.9)
- In **Trial 3**, clinical success at ECR timepoint was seen in **87.3%** of Nuzyra-treated patients vs **82.2%** of linezolid-treated patients (5.1, 95% CI, -0.2, 10.5)

Clinical Studies

- Clinical response at PTE (7 to 14 days after last dose):
  - **Trial 2:** 86.1% of Nuzyra-treated patients vs 83.6% of linezolid-treated patients (difference 2.5, 95% CI, -3.2, 8.2)
  - **Trial 3:** 83.9% vs 80.5%, respectively (difference 3.4, 95% CI, -2.3, 9.1)
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monographs:

  https://www.empr.com/drug/nuzyra-tablets/
  https://www.empr.com/drug/nuzyra-injection/