***IN VITRO* ACTIVITY**
IN GRAM-POSITIVE, GRAM-NEGATIVE, AND ATYPICAL BACTERIA[1,2]

INDICATIONS AND USAGE

NUZYRA® is a tetracycline-class antibacterial indicated for the treatment of adult patients with the following infections caused by susceptible microorganisms:

Community-Acquired Bacterial Pneumonia (CABP) caused by the following: *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: *Staphylococcus 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 *Klebsiella pneumoniae.*

USAGE

To reduce the development of drug-resistant bacteria and maintain the effectiveness of NUZYRA and other antibacterial drugs, NUZYRA should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

NUZYRA is contraindicated in patients with known hypersensitivity to omadacycline or tetracycline-class antibacterial drugs, or to any of the excipients.

Please see Important Safety Information throughout and full Prescribing Information at NUZYRA.com.

once-daily
NUZYRA®
(omadacycline)
100 mg for injection / 150 mg tablets

The clinical relevance of these *in vitro* data is unknown. Treatment decisions should not be based on this information.

GRAM-POSITIVE[1,a]	N	MIC_{90} µg/mL	%S	%R
Staphylococcus aureus	5011	0.12	98.1 96.4	0.3[b] 1.9[c]
Methicillin-susceptible (MSSA)	2983	0.12	99.8 99.2	0.1[b] 0.2[c]
Methicillin-resistant (MRSA)	2028	0.25	95.6	0.6[b]
Enterococcus faecalis	762	0.12	100.0	0.0[b]
Enterococcus faecium	319	0.12	---	---
Vancomycin-resistant	208	0.12	---	---
Streptococcus pneumoniae	949	0.06	99.9	0.0[c]
Erythromycin-resistant	425	0.06	100.0	0.0[c]
Penicillin-resistant	99	0.06	100.0	0.0[c]
Tetracycline-resistant	191	0.06	100.0	0.0[c]
Streptococcus pyogenes	277	0.12	99.6	0.0[b]
Erythromycin-resistant	88	0.12	100.0	0.0[a]
Clindamycin-resistant	25	0.12	100.0	0.0[a]
Tetracycline-resistant	105	0.12	99.0	0.0[a]
Streptococcus agalactiae	263	0.12	---	---

CLSI=Clinical and Laboratory Standards Institute; FDA=Food and Drug Administration; MIC=minimal inhibitory concentration; R=resistant; S=susceptible.
[a]Criteria as published by CLSI (2023) and US FDA (2023). [b]Using FDA ABSSSI breakpoints. [c]Using FDA CABP breakpoints.

The clinical relevance of these *in vitro* data is unknown. Treatment decisions should not be based on this information.

GRAM-NEGATIVE[1,a]	N	MIC_{90} µg/mL	%S	%R
Haemophilus influenzae	637	1	99.8	0.0[c]
Beta-lactamase-positive	176	1	100.0	---
Beta-lactamase-negative	461	1	99.8	0.0[c]
Haemophilus parainfluenzae	82	2	95.1	1.2[c]
Klebsiella pneumoniae	1545	4	91.2	4.2[b,c]
ESBL-phenotype	286	16	79.0	10.5[b,c]
Klebsiella oxytoca	377	2	---	---
Escherichia coli	3482	1	---	---
ESBL-phenotype	643	2	---	---
Moraxella catarrhalis	319	0.25	---	---
Enterobacter (Klebsiella) aerogenes	300	2	---	---
Enterobacter cloacae	168	4	94.0	2.4[b]
Citrobacter koseri	165	1	---	---
ATYPICAL[1,d]	**N**	**MIC_{90} µg/mL**	**%S**	**%R**
***Chlamydia pneumoniae*[3,e]**	15	0.25	---	---
***Legionella pneumophila*[4,f]**	100	0.25	---	---
***Mycoplasma pneumoniae*[5,g,h]**	20	0.25	---	---

ESBL=extended spectrum beta-lactamase.
[d]Criteria as published by CLSI (2023). [e]US isolates, collection dates not available. [f]Clinical isolates, 1995-2014.
[g]Criteria as published by CLSI (2011). [h]US and Chinese reference strains and clinical isolates, 2016.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Mortality imbalance was observed in the CABP clinical trial with eight deaths (2%) occurring in patients treated with NUZYRA compared to four deaths (1%) in patients treated with moxifloxacin. The cause of the mortality imbalance has not been established. All deaths, in both treatment arms, occurred in patients >65 years of age; most patients had multiple comorbidities. The causes of death varied and included worsening and/or complications of infection and underlying conditions. Closely monitor clinical response to therapy in CABP patients, particularly in those at higher risk for mortality.

Please see Important Safety Information throughout and full Prescribing Information at NUZYRA.com.

once-daily
NUZYRA®
(omadacycline)
100 mg for injection / 150 mg tablets

IMPORTANT SAFETY INFORMATION *(con't)*

WARNINGS AND PRECAUTIONS *(con't)*

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

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

Hypersensitivity reactions have been reported with NUZYRA. Life-threatening hypersensitivity (anaphylactic) reactions have been reported with other tetracycline-class antibacterial drugs. NUZYRA is structurally similar to other tetracycline-class antibacterial drugs and is contraindicated in patients with known hypersensitivity to tetracycline-class antibacterial drugs. Discontinue NUZYRA if an allergic reaction occurs.

Clostridioides 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. Evaluate if diarrhea occurs.

NUZYRA is structurally similar to tetracycline-class antibacterial drugs and may have similar adverse reactions. Adverse reactions, including photosensitivity, fixed drug eruption, pseudotumor cerebri, and anti-anabolic action (which has led to increased BUN, azotemia, acidosis, hyperphosphatemia, pancreatitis, and abnormal liver function tests), have been reported for other tetracycline-class antibacterial drugs, and may occur with NUZYRA. Discontinue NUZYRA if any of these adverse reactions are suspected.

Prescribing NUZYRA in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥2%) are nausea, vomiting, infusion site reactions, alanine aminotransferase increased, aspartate aminotransferase increased, gamma-glutamyl transferase increased, hypertension, headache, diarrhea, insomnia, and constipation.

References: 1. 2020 and 2021 US Surveillance Data. Data on file. Paratek Pharmaceuticals, Inc. **2.** NUZYRA [Prescribing Information]. Paratek Pharmaceuticals, Inc. **3.** Kohlhoff SA, Huerta N, Hammerschlag MR. In vitro activity of omadacycline against *Chlamydia pneumoniae*. *Antimicrob Agents Chemother*. 2019;63(2):e01907-e01918. **4.** Dubois J, Dubois M, Martel JF. *In vitro* and intracellular activities of omadacycline against Legionella pneumophila. *Antimicrob Agents Chemother*. 2020;64(5):e01972-19. **5.** Waites KB, Crabb DM, Liu Y, Duffy LB. In vitro activities of omadacycline (PTK 0796) and other antimicrobial agents against human mycoplasmas and ureaplasmas. *Antimicrob Agents Chemother*. 2016;60(12):7502-7504.

PARATEK®

US-NUA-1010-01 04/25

Please see full Prescribing Information at NUZYRA.com.

once-daily
NUZYRA®
(omadacycline)
100 mg for injection / 150 mg tablets