NUZYRA® ORAL DOSING IN CABP

ONCE-DAILY DOSING[1]*: Treatment duration: 7-14 days[1]

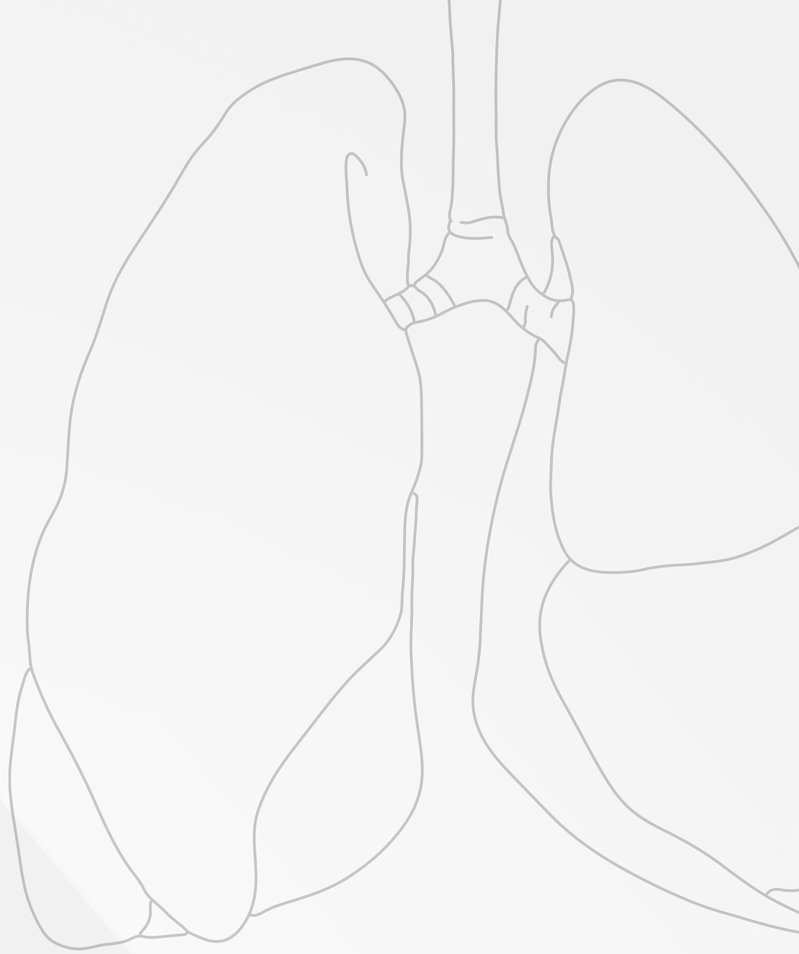
DAY 1: Loading Dose
300 mg (2 tablets)
TWICE on Day 1

+

Once-Daily Maintenance Dose
300 mg (2 tablets)

Tablets are not shown at actual size.

*For treatment of CABP, the oral loading dose is 300 mg twice on Day 1.[1]



HOW TO PRESCRIBE

℞ **NUZYRA 300 mg**
*PO **BID** x 1 day*

THEN

NUZYRA 300 mg
PO QD

7-14 days total

TOTAL TABLETS: 16-30

NUZYRA is available today at our network specialty pharmacies

Visit nuzyra.com/find

THE SANFORD GUIDE | **MERCK MANUAL** | **UpToDate®** | **IDSA**

RECOGNIZE NUZYRA AS AN FDA-APPROVED **TREATMENT FOR CABP.[2-8]***

*As of April 2024.

BID=twice a day; PO=per os; QD=once a day.

INDICATION and USAGE

INDICATION: NUZYRA® (omadacycline) is a tetracycline-class antibacterial indicated for the treatment of Community-Acquired Bacterial Pneumonia (CABP) in adults caused by certain susceptible microorganisms. See complete *Indication and Usage*.

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 and full Prescribing Information at NUZYRA.com.

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

WHEN PRESCRIBING ORAL NUZYRA, INSTRUCT PATIENTS TO[1]:

- Fast for at least 4 hours and then take with water
  - NUZYRA can be taken at bedtime or upon waking

- Not eat or drink (except water) for 2 hours after dosing

- Not consume dairy products, antacids, or multivitamins for 4 hours after dosing

Patients on anticoagulant therapy may require downward adjustment of their anticoagulant dosage while also taking NUZYRA.

PATIENTS WITH RENAL OR HEPATIC IMPAIRMENT
DO NOT REQUIRE A DOSE ADJUSTMENT.[1]

NUZYRA is also available in an intravenous (IV) formulation[1]

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

INDICATION and USAGE

INDICATION: NUZYRA® (omadacycline) is a tetracycline-class antibacterial indicated for the treatment of Community-Acquired Bacterial Pneumonia (CABP) in adults 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*.

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.

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.

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, 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.

DRUG INTERACTIONS

Patients who are on anticoagulant therapy may require downward adjustment of their anticoagulant dosage while taking NUZYRA.

Absorption of tetracyclines, including NUZYRA is impaired by antacids containing aluminum, calcium, or magnesium, bismuth subsalicylate and iron containing preparations.

USE IN SPECIFIC POPULATIONS

Lactation: Breastfeeding is not recommended during treatment with NUZYRA.

References: 1. NUZYRA [Prescribing Information]. Paratek Pharmaceuticals, Inc. **2.** Sanford Guide. Pneumonia, community-acquired, adult, out-patient. Accessed May 10, 2023. https://webedition.sanfordguide.com/en/sanford-guide-online/disease-clinical-condition/pneumonia-communityacquired **3.** Sanford Guide. Pneumonia, community-acquired, adult, in-patient. Accessed May 10, 2023. https://webedition.sanfordguide.com/en/sanford-guide-online/disease-clinical-condition/pneumonia-community-acquired **4.** Merck Manuals Professional Edition. Community-Acquired Pneumonia. Accessed April 8, 2024. https://www.merckmanuals.com/professional/pulmonary-disorders/pneumonia/community-acquired-pneumonia?query=omadacycline **5.** UpToDate®. Community-acquired pneumonia: Empiric outpatient antibiotic selection in adults. Accessed October 6, 2023. https://sso.uptodate.com/contents/image/ print?imageKey=ID%2F111829&topicKey=7031&search=Omadacycline&rank=12~19&source=see_link **6.** UpToDate®. Treatment of community-acquired pneumonia in adults who require hospitalization. Accessed October 6, 2023. https://sso.uptodate.com/contents/treatment-of-community-acquired-pneumonia-in-adults-who-require-hospitalization **7.** UpToDate®. Treatment of community acquired pneumonia in adults in the outpatient setting. Accessed October 6, 2023. https://sso.uptodate.com/contents/treatment-ofcommunity-acquired-pneumonia-in-adults-in-the-outpatient-setting **8.** Infectious Diseases Society of America (IDSA). CAP clinical pathway. Accessed April 8, 2024. https://www.idsociety.org/globalassets/idsa/practice-guidelines/community-acquired-pneumoniain-adults/cap-clinical-pathway-final-online.pdf

PARATEK®

US-NUA-1063 08/24

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once-daily
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150 mg tablets