NUZYRA® (omadacycline) must be reconstituted and then further diluted without adding preservatives.

**Dosage Regimen**

### Community-Acquired Bacterial Pneumonia (CABP)

**Daily Adult Dose**: 200 mg by intravenous infusion over 30 minutes twice on Day 1 over a period of 30 minutes, followed by 300 mg orally once daily.

**Maintenance Dose**: 300 mg orally once daily.

### Acute Bacterial Skin and Skin Structure Infections (ABSSSI)

**Loading Dose**: 450 mg orally on Day 1 and Day 2.

**Maintenance Dose**: 300 mg orally once daily.

**Daily Adult Dose**: 200 mg by intravenous infusion over 30 minutes twice on Day 1.

**Maintenance Dose**: 300 mg orally once daily.

### IV Preparation

**Preparation**

1. **NUZYRA®**: (omadacycline) must be reconstituted and then further diluted without adding preservatives.

2. **Loading Dose**:
   - Day 1: 200 mg by intravenous infusion over 30 minutes twice
   - Day 2: 450 mg orally

3. **Maintenance Dose**: 300 mg orally once daily.

**Compatibility**

- **Do NOT** administer with any solution containing multivalent cations, e.g., calcium, magnesium, potassium, or sodium. Check the manufacturer’s compatibility list for NUZYRA® and other solutions.

**Additional Information**

- If the NUZYRA solution is not yellow to dark orange, the reconstituted solution should be discarded.

**Storage and Handling**

- **Storage of the Diluted Infusion Solution**
  - Do not freeze.

- **Stability**
  - Solution stability: 4 hours (Ambient) at 2°C to 25°C (36°F to 77°F)

**DRUG INTERACTIONS**

**INTERACTIONS**

- **Drug Interactions**: Use caution when administering NUZYRA and other drugs that affect coagulation.

**DOSAGE AND ADMINISTRATION**

**INFECTION LOADING DOSES**

- **Day 1** and **Day 2**: 450 mg orally

- **Maintenance Dose**: 300 mg orally once daily.

**CONTRAINDICATIONS**

- **Contraindicated in the treatment of community-acquired bacterial pneumonia caused by Haemophilus influenzae, Streptococcus pyogenes, Streptococcus luetonensis, and Staphylococcus aureus (methicillin-susceptible isolates).**

**ADVERSE REACTIONS**

- **Frequently Observed Adverse Reactions**: Hypersensitivity reactions, diarrhea, constipation, dizziness, headache.

**IMPORTANT SAFETY INFORMATION (cont.)**

- **Infusion Infections**: Administer through a dedicated line or through a Y-site compatible with NUZYRA® and its design logo are registered trademarks of Paratek Pharmaceuticals, Inc. US-NUA-0351-1   12/20

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QUESTIONS?
Call NUZYRA Central™ Support Services at 1-877-4-NUZYRA (1-877-468-9972), Mon-Fri, 9 am to 8 pm ET to speak with a representative.

PARTICIPATING SPECIALTY DISTRIBUTORS
• NUZYRA® (omadacycline) for Injection is supplied as a 100 mg single-dose vial, packaged in cartons of 10, and may be ordered from select specialty distributors
• Contact a specialty distributor from the list below to order

SPECIALTY DISTRIBUTOR NETWORK
SPECIALTY DISTRIBUTOR NETWORK

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. 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.

Please see Important Safety Information continued throughout and accompanying Full Prescribing Information.

NUZYRA® (omadacycline) PACKAGING WITH NATIONAL DRUG CODES (NDCs)

NUZYRA PACKAGING NDC WHOLESALE ACQUISITION COST
100 mg single-dose vial Cartons containing 10 vials 71715-001-02 $3,660.10*

NUZYRA 10-DIGIT NDC NUZYRA 11-DIGIT NDC WITH LEADING ZERO
71715-001-02 71715-0001-02

*As of January 1, 2021

IMPORTANT SAFETY INFORMATION (cont.)
WARNINGS AND PRECAUTIONS (cont.)
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, including NUZYRA, and may range in severity from mild diarrhea to fatal colitis. Evaluate if diarrhea occurs.

NUZYRA is structurally similar to tetracycline-class of 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.

Please see Important Safety Information continued throughout and accompanying Full Prescribing Information.

FOR INJECTION
FOR INJECTION

IMPORTANT SAFETY INFORMATION (cont.)
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NUZYRA is contraindicated in patients with known hypersensitivity to omadacycline or tetracycline-class antibacterial drugs, or to any of the excipients.

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- Contact a specialty distributor from the list below to order

Paratek does not recommend or prefer the use of one distributor over another.

---

**IMPORTANT SAFETY INFORMATION**

**CONTRAINDICATIONS**

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**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. Please see Important Safety Information continued throughout and accompanying Full Prescribing Information.

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**FOR INJECTION**

NUZYRA® (omadacycline) packaging with National Drug Codes (NDCs)

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<th>NDC</th>
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<tr>
<td>100 mg single dose vial</td>
<td>71715-001-02</td>
<td>$3,660.10*</td>
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*As of January 1, 2021

Some payers require physicians to report 11-digit NDCs when listing a drug on a claim form. To do this, add a zero to the middle section:

- NUZYRA 10-DIGIT NDC
- NUZYRA 11-DIGIT NDC WITH LEADING ZERO

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DOSEAGE REGIMEN

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**INFUSION INSTRUCTIONS**

(NUZYRA® and NUZYRA Tablets are available oral solution 200 mg/5 mL, 320 mg/5 mL, 480 mg/5 mL, 640 mg/5 mL, 800 mg/5 mL, 1,000 mg/5 mL, and 1,200 mg/5 mL). Discard any unused portion of reconstituted solution. Do not freeze.

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NUZYRA® (omadacycline) DOSAGE AND ADMINISTRATION

**DOSAGE REGIMEN**

**ABSSSI**
- **Day 1 and Day 2:** 450 mg orally twice daily
- **Day 1:** 200 mg by intravenous infusion over 60 minutes

**CABP**
- **Day 1:** 200 mg by intravenous infusion over 60 minutes twice
- **Day 2:** 300 mg orally once daily

**Intravenous Administration Guide**

- **Intravenous**—NUZYRA® (omadacycline) must be reconstituted and then further diluted under aseptic conditions.
- **Intramuscular**—The compatibility of NUZYRA® with other drugs and infusion solutions other than 0.9% Sodium Chloride Injection, USP, or 5% Dextrose Injection, USP has not been established.
- **Oral**—Efficacy and safety of an oral loading dose was not evaluated in CABP and ABSSSI.

**STORAGE AND HANDLING**

- **Storage**—NUZYRA® for Injection and NUZYRA Tablets should be stored 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F).
- **Administration**—NUZYRA® for Injection and NUZYRA Tablets should be administered within 24 hours of reconstitution.

**ADVERSE REACTIONS**

- **Infections and Infestations**—The safety and effectiveness of NUZYRA® have not been established in patients with HIV infection.
- **Hypersensitivity**—If a serious or life-threatening hypersensitivity reaction occurs, immediately discontinue the drug and institute appropriate therapy.
- **Drug Interactions**—The compatibility of NUZYRA® with other drugs and infusion solutions other than 5% Dextrose Injection, USP, or 5% Dextrose Injection, USP, for Injection has not been established.

**Intravenous Administration Guide**

- **Reconstitution of NUZYRA® for Injection**
  - **For Parenteral Use Only**
  - **Reconstitute each 100 mg vial with 5 mL of Sterile Water, 0.9% Sodium Chloride Injection, USP, or 5% Dextrose Injection, USP, bag for injection.**
  - **The concentration of the final diluted infusion will either be 1 mg/mL or 2 mg/mL, as per the table below. Discard any unused portion of reconstituted solution.**

**IV PREPARATION**

- **Preparation**
  - **Nuzyra® (omadacycline)** must be reconstituted and then further diluted under aseptic conditions. Reconstitute and dilute the appropriate number of vials as determined from the table below.
  - **Reconstitute each 100 mg vial with 5 mL of Sterile Water, 0.9% Sodium Chloride Injection, USP, or 5% Dextrose Injection, USP.**

**STORAGE AND THE DILUTED INFUSION SOLUTION**

- **Storage**—The diluted infusion solution should be stored at room temperature (≤25°C) before and after reconstitution.
- **Use within 24 hours after reconstitution**

**IV INFUSION INSTRUCTIONS**

**After Reconstitution and Dilution**

- **Intravenous**—Administer through a dedicated line or through a Y-site infusion system that allows for separate and simultaneous administration of other drugs.

**IMPORTANT SAFETY INFORMATION**

**Infectious Disease**

- **Community-Acquired Respiratory Tract Infections**
  - **In patients with HIV infection:**
  - **In patients with HIV infection:**
  - **In patients with HIV infection:**

**Indications and Usage**

- **NUZYRA® (omadacycline)** is an oral, once-daily, non-β-lactam, bactericidal, tetracycline-class antibacterial indicated for the treatment of adult patients with community-acquired respiratory tract infections (URIs) and skin and skin structure infections (SSSIs) caused by susceptible bacteria.

**Designation and Use**

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NUZYRA® (omadacycline) DOSAGE AND ADMINISTRATION

DOSAGE REGIMEN

NUZYRA® (omadacycline) must be reconstituted and then further diluted under aseptic conditions. Reconstitute each 100 mg vial with 5 mL of Sterile Water, 0.9% Sodium Chloride Injection, USP, or 5% Dextrose Injection, USP. Use within 30 minutes after reconstitution. Discard any unused portion of reconstituted solution. Do not freeze.

STORAGE AND HANDLING

• Store at 2°C to 8°C (36°F to 46°F) before reconstitution and for up to 30 minutes after reconstitution. Discard within 30 minutes after reconstitution.

DOSEAGE OF NUZYRA IN CABP AND ABSSSI PATIENTS TREATMENT SOLUTION 1 TO 6 DAYS

PREPARATION

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WARNING: Discard if vial is cracked or the seal is broken.

PRECAUTIONS

Injection, USP, or 0.9% Sodium Chloride Injection, USP, has not been established through the same intravenous line

COMPARABILITY OF NUZYRA WITH OTHER DRUGS AND INFUSION SOLUTIONS

The compatibility of NUZYRA with other drugs and infusion solutions other than 5% Dextrose through and accompanying Full Prescribing Information.

Please see Important Safety Information continued

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INFECTION LOADING DOSES MAINTENANCE DOSE

CABP

100 mg by intravenous infusion over 30 minutes twice on Day 1

300 mg orally once daily

ABSSSI

100 mg by intravenous infusion over 30 minutes twice on Day 1

300 mg orally once daily

NUZYRA® (omadacycline) is contraindicated in patients with a history of anaphylaxis or angioedema due to NUZYRA or any of its excipients.

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Although there is an alternative IV loading dose for CABP and ABSSSI of 100 mg to be administered over 30 minutes for a 100 mg dose

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In CABP and ABSSSI, NUZYRA is administered for up to 5 days in a row. In CABP, use for a minimum of 7 days.

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