# DOSING GUIDE

**NUZYRA offers you the flexibility of oral and IV dosing options.[1]**


*Vial and tablets are not shown at actual size.*

NUZYRA® (omadacycline) 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 Indications and Usage and Important Safety Information and full Prescribing Information at NUZYRA.com.*

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

# ORAL DOSING

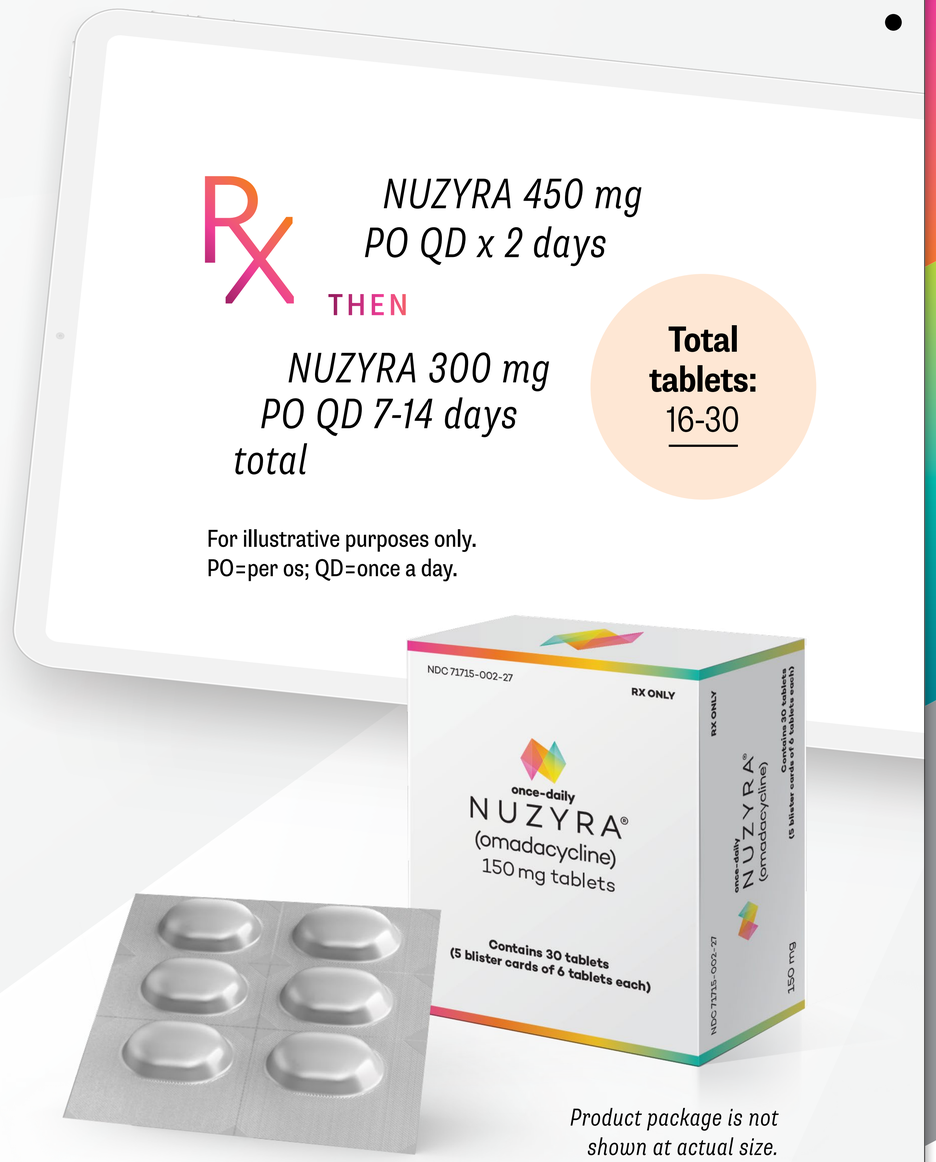
## Dosage of oral NUZYRA in adult ABSSSI patients

**Treatment duration:** 7 to 14 days[1]

**DAYS 1-2**
450 mg (3 tablets) once per day


**Maintenance Dose**
300 mg (2 tablets) once daily


*Tablets are not shown at actual size.*




*Product package is not shown at actual size.*

## 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.

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

# IV DOSING

## Dosage of NUZYRA IV in adult ABSSSI patients

**Treatment duration:** 7 to 14 days[1]

| Infection | Loading Doses | Maintenance Dose |
|---|---|---|
| ABSSSI | **Day 1:** 200 mg by IV infusion over 60 minutes<br>**OR**<br>100 mg by IV infusion over 30 minutes **TWICE** | 100 mg by IV infusion over 30 minutes once daily |


*Vials are not shown at actual size.*

## Important considerations when administering NUZYRA IV[1]:

- Do NOT administer with any solution containing multivalent cations, (e.g., calcium and magnesium), through the same intravenous line
- The compatibility of NUZYRA IV with other drugs and infusion solutions other than 5% Dextrose Injection, USP, or 0.9% Sodium Chloride Injection, USP, has not been established

**Patients with renal or hepatic impairment**

**DO NOT REQUIRE A DOSE ADJUSTMENT WITH NUZYRA (ORAL OR IV)[1]**

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

# ORAL DOSING

## Dosage of oral NUZYRA in adult CABP patients

**Treatment duration:** 7 to 14 days[1]

**TWICE on Day 1***
300 mg (2 tablets)


**Maintenance Dose**
300 mg (2 tablets) once daily


*Tablets are not shown at actual size.*

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


*Product package is not shown at actual size.*

## 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.

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

# IV DOSING

## Dosage of NUZYRA IV in adult CABP patients

**Treatment duration:** 7 to 14 days[1]

| Infection | Loading Doses | Maintenance Dose |
|---|---|---|
| CABP | **Day 1:** 200 mg by IV infusion over 60 minutes<br>**OR**<br>100 mg by IV infusion over 30 minutes **TWICE** | 100 mg by IV infusion over 30 minutes once daily |


*Vials are not shown at actual size.*

## Important considerations when administering NUZYRA IV[1]:

- Do NOT administer with any solution containing multivalent cations, (e.g., calcium and magnesium), through the same intravenous line
- The compatibility of NUZYRA IV with other drugs and infusion solutions other than 5% Dextrose Injection, USP, or 0.9% Sodium Chloride Injection, USP, has not been established

**Patients with renal or hepatic impairment**

**DO NOT REQUIRE A DOSE ADJUSTMENT WITH NUZYRA (ORAL OR IV)[1]**

*Please see Indications and Usage and Important Safety Information and full Prescribing Information at NUZYRA.com.*

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

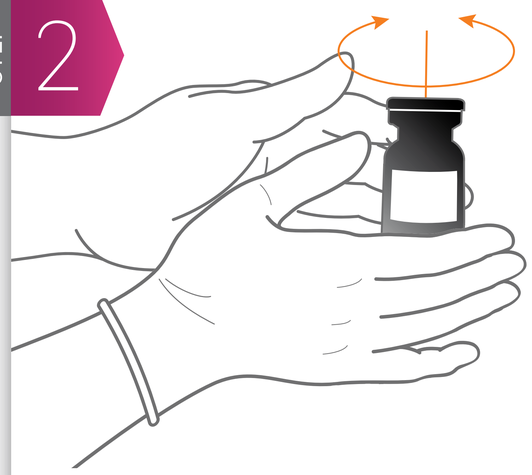
# PREPARING, STORING, AND HANDLING OF **NUZYRA IV**

## Steps for reconstitution and dilution[1]

STEP 1

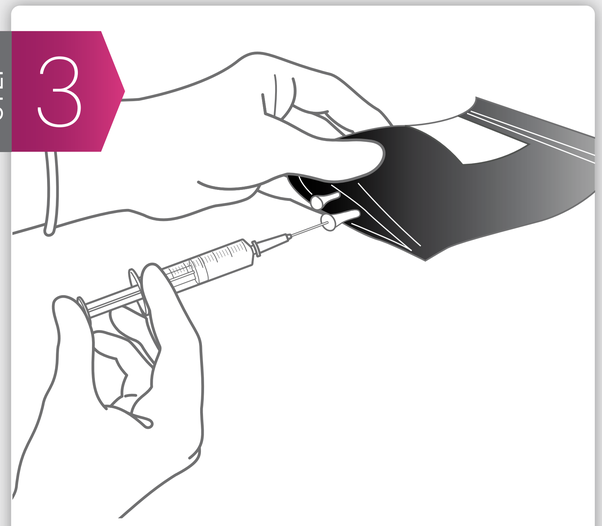
- Reconstitute each 100 mg vial with 5 mL of Sterile Water, 0.9% Sodium Chloride Injection, USP, or 5% Dextrose Injection, USP, for injection

STEP 2



- Gently swirl contents and let the vial stand until the cake has completely dissolved and any foam disperses
- Do not shake the vial
- If the NUZYRA IV solution is not yellow to dark orange, the reconstituted solution should be discarded
- Prior to further dilution and administration, visually inspect for particulate matter and discoloration
- If necessary, invert the vial to dissolve any remaining powder and swirl gently to prevent foaming

STEP 3



- Immediately (within 1 hour), withdraw 5 or 10 mL of reconstituted solution and further dilute to a 100 mL (nominal volume) of 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 on the next page
- Discard any unused portion of reconstituted solution


*Vial is not shown at actual size.*

## Always remember:

- ✓ NUZYRA IV must be reconstituted and then further diluted under aseptic conditions. Reconstitute and dilute the appropriate number of vials using the table on the next page.
- ✓ As with all parenteral drug products, whenever solution and container permit, inspect visually for particulate matter and discoloration prior to administration

# PREPARING, STORING, AND HANDLING OF **NUZYRA IV** *(con't)*

## Reconstitution and dilution: Preparation of NUZYRA IV Infusion[1]

| NUZYRA FOR INJECTION DOSE | 200 mg | 100 mg |
|---|---|---|
| **Number of vials to reconstitute for further dilution** | 2 vials | 1 vial |
| **Volume of reconstituted solution (5 mL/vial) to withdraw for further dilution** | 10 mL | 5 mL |
| **Final infusion concentration of NUZYRA IV** | 2 mg/mL | 1 mg/mL |

## Storage and handling[1]

- NUZYRA for injection and NUZYRA tablets should be stored at 20°C to 25°C (68°F to 77°F), with excursions permitted to 15°C to 30°C (59°F to 86°F)
- Do not freeze

## Storage of the diluted infusion solution[1]

- If at room temperature (≤25°C [77°F]), use within 24 hours
- If refrigerated (2°C to 8°C [35.6°F to 46.4°F]), use within 7 days
- Do not freeze

## Administration instructions (after reconstitution and dilution)[1]

- After reconstitution and dilution, administer NUZYRA by intravenous infusion, using a total infusion time of 60 minutes for a 200-mg dose, or a total infusion time of 30 minutes for a 100-mg dose
- Administer through a dedicated line or through a Y-site
  - If the same intravenous line is used for sequential infusion of several drugs, flush the line before and after NUZYRA IV infusion with 0.9% Sodium Chloride Injection, USP, or 5% Dextrose Injection, USP
  - The compatibility of NUZYRA IV with other drugs and infusion solutions other than 5% Dextrose Injection, USP, or 0.9% Sodium Chloride Injection, USP, has not been established


*Vials and product package are not shown at actual size.*

Need assistance placing your order or have questions? **Call NUZYRA Central® at**

**1-877-4NUZYRA** (1-877-468-9972)

**M-F, 8 AM - 8 PM ET**

## INDICATIONS and USAGE

NUZYRA® (omadacycline) 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.

### 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, 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.

### 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.** LaPlante KL, Dhand A, Wright K, et al. Re-establishing the utility of tetracycline-class antibiotics for current challenges with antibiotic resistance. *Ann Med*. 2022;54(1):1686-1700.

PARATEK®



US-NUA-0979-01 04/25

*Please see full Prescribing Information at NUZYRA.com.*

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

# Prescribe once-daily* NUZYRA

## A NEXT-GENERATION TETRACYCLINE

**WITH**

## BROAD-SPECTRUM ACTIVITY

INCLUDING CERTAIN RESISTANT PATHOGENS

**THAT MAY BE APPROPRIATE TO**

## PRESCRIBE EMPIRICALLY

FOR ADULT PATIENTS WITH ABSSSI OR CABP[1,2]

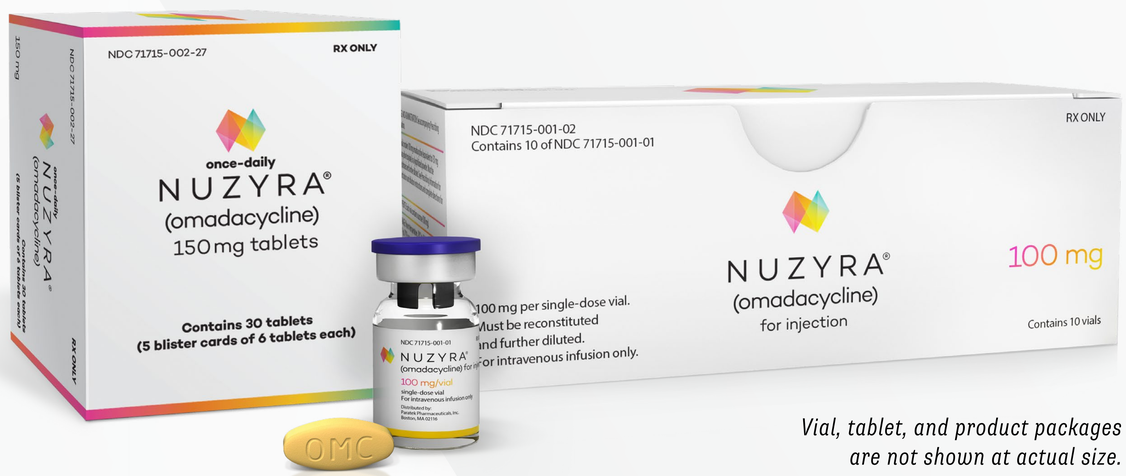
*For treatment of CABP, the oral loading dose is 300 mg twice on Day 1.[1]

once-daily

# NUZYRA®

(omadacycline)

100 mg for injection / 150 mg tablets




*Vial, tablet, and product packages are not shown at actual size.*

NUZYRA® is indicated for treatment of Community-Acquired Bacterial Pneumonia (CABP) and Acute Bacterial Skin and Skin Structure Infections (ABSSSI) in adults caused by select susceptible microorganisms.

**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

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