ADMINISTRATION TO HELP FIT YOUR PATIENTS' NEEDS

Dosing, Administration, and Ordering Guide

Vial and tablets are actual size.

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.

Please see Important Safety Information throughout and accompanying full Prescribing Information.

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

For your adult patients with ABSSSI or CABP

PROVEN BROAD-SPECTRUM COVERAGE WITH A MODERNIZED TETRACYCLINE

Once-daily* NUZYRA: Broad-spectrum activity against tough-to-treat pathogens[1]

- Prevalence of antibiotic-resistant pathogens has heightened the need for alternative monotherapy options
- NUZYRA is a novel approach designed to overcome the most common mechanisms of tetracycline resistance[1-3]
  - Active efflux pumps
  - Ribosomal protection proteins
- Available in 2 bioequivalent formulations–oral and IV[1]
- Early clinical response within days of first dose[1]
- An alternative to fluoroquinolones and for patients with beta-lactam or sulfonamide allergies[1]
- Appropriate for a wide range of patients[1]

IV=intravenous.

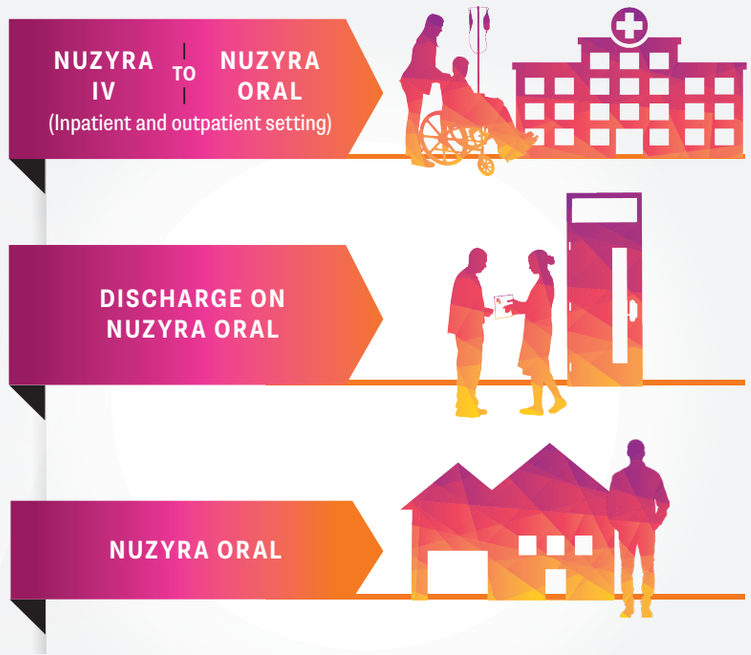
*For treatment in CABP, the oral loading dose is 300 mg twice on Day 1.[1]

PRESCRIBE ONCE-DAILY **NUZYRA EMPIRICALLY.**

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

FLEXIBILITY TO HELP SUPPORT YOUR PATIENTS' ANTIBIOTIC NEEDS

May help keep patients on track to clinical cure*†



*In OASIS-1 and OASIS-2, clinical cure at the post-treatment evaluation was defined as survival after completion of study treatment without receiving any other antibacterial therapy or unplanned major surgical intervention, and having sufficient resolution of infection such that further antibacterial therapy was not needed.[1]

†In OPTIC, clinical cure at the post-treatment evaluation (PTE), measured 5 to 10 days after last dose of study drug, was defined as survival and improvement in signs and symptoms of CABP, based on the clinician's judgment, to the extent that further antibacterial therapy is not necessary.[1]

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.

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ONCE-DAILY IV DOSING IN ABSSSI OR CABP*

Dosage of NUZYRA IV in adult ABSSSI and CABP patients

Treatment duration: 7 to 14 days[1]

Infection	Loading Doses	Maintenance Dose
ABSSSI	**Day 1:** 200 mg by IV infusion over 60 minutes — OR — **100 mg** by IV infusion over 30 minutes TWICE	**100 mg** by IV infusion over 30 minutes once daily
CABP*	**Day 1:** 200 mg by IV infusion over 60 minutes — OR — **100 mg** by IV infusion over 30 minutes TWICE	**100 mg** by IV infusion over 30 minutes once daily

*See page 11 for more information on oral dosing.

Important considerations when administering NUZYRA IV[1]

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

Vial is not shown at actual size.

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

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

PREPARING NUZYRA IV

Steps to reconstitute[1]

1. NUZYRA must be reconstituted and then further diluted under aseptic conditions. Reconstitute and dilute the appropriate number of vials using the table below.
2. Reconstitute each 100 mg vial with 5 mL of Sterile Water, 0.9% Sodium Chloride Injection, USP, or 5% Dextrose Injection, USP, for injection.
3. Gently swirl contents and let the vial stand until the cake has completely dissolved and any foam disperses. Do not shake the vial.
4. If the NUZYRA solution is not yellow to dark orange, the reconstituted solution should be discarded. Prior to further dilution and administration, inspect for particulate matter and discoloration. If necessary, invert the vial to dissolve any remaining powder and swirl gently to prevent foaming.
5. Immediately (within 1 hour), withdraw 5 or 10 mL of reconstituted solution and further dilute with 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 below. Discard any unused portion of reconstituted solution.
6. As with all parenteral drug products, whenever solution and container permit, inspect visually for particulate matter and discoloration prior to administration.

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	2 mg/mL	1 mg/mL

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.

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PROPER **STORAGE AND HANDLING**

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

Infusion instructions (after reconstitution and dilution)[1]

- 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 infusion with 0.9% Sodium Chloride Injection, USP, or 5% Dextrose Injection, USP
  - The compatibility of NUZYRA with other drugs and infusion solutions other than 5% Dextrose Injection, USP, or 0.9% Sodium Chloride Injection, USP, has not been established

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)
- When NUZYRA IV (100 mL) is prepared in an infusion bag, room temperature stability is 24 hours or 7 days when refrigerated[5]
- Do not freeze

Vial and product package are not shown at actual size.

WARNINGS AND PRECAUTIONS *(con't)*

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.

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

NUZYRA IV IN INFUSION CENTERS

A study showed stability and sterility when used with elastomeric infusion pumps*[5]

After reconstitution and with refrigeration, NUZYRA IV used with an elastomeric infusion pump demonstrated no increase in challenge-microorganism populations.

*The SMARTeZ® elastomeric infusion pump was used in this study.

NUZYRA IV MAINTENANCE DOSING IS A ONCE-DAILY, 30-MINUTE INFUSION.[1]

Reimbursed through a range of providers

NUZYRA IV is reimbursed through many government and third-party commercial insurance plans, including:

Commercial insurance Coverage is typical under the Medical Benefit and may not require prior authorization.

Medicare Part B Medicare Advantage or Medicare with supplemental coverage often lowers drug cost significantly, sometimes costing patients $0.

Medicaid With Managed Medicaid or not, prior authorization detailing lack of response with previous prescription therapies is often required.

CONTACT YOUR KEY ACCOUNT MANAGER FOR MORE INFORMATION.

once-daily
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100 mg for injection / 150 mg tablets

NUZYRA IV: ORDERING VIA SPECIALTY DISTRIBUTOR NETWORK

CONTACT ONE OF THE SPECIALTY DISTRIBUTORS BELOW TO ORDER NUZYRA IV			
VENDOR	**PHONE**	**FAX**	**WEBSITE**
ASD Healthcare (AmerisourceBergen)	800-746-6273	800-547-9413	www.asdhealthcare.com
Besse Medical	513-851-2345	513-851-3299	www.besse.com
Cardinal Health Specialty	866-677-4844	614-652-7608	www.cardinalhealth.com
Metro Medical, a Cardinal Health company	800-768-2002	615-256-4194	www.metromedical.com
CuraScriptSD	877-599-7748	800-862-6208	www.curascriptsd.com
McKesson Plasma and Biologics	877-625-2566	888-752-7626	www.mckesson.com
McKesson Specialty Health	800-482-6700	800-289-9285	mscs.mckesson.com
Morris & Dickson Specialty Distribution, LLC (MDSD)	800-710-6100	318-524-3096	www.mdspecialtydist.com

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

NUZYRA IV IS SUPPLIED AS A **100 MG SINGLE-DOSE VIAL, PACKAGED IN CARTONS OF 10.**

Vial is not actual size.

WARNINGS AND PRECAUTIONS *(con't)*

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.

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

NATIONAL DRUG CODES (NDC) FOR ORDERING*

NUZYRA PACKAGING	NDC
100 mg single-dose vial cartons containing 10 vials	71715-001-02

*As of January 1, 2020.

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
71715-001-02	71715-0001-02

NUZYRA CENTRAL®

Questions? Call NUZYRA Central® Support Services at 1-877-4-NUZYRA (1-877-468-9972), Mon-Fri, 8 AM to 8 PM ET to speak with a representative.

WARNINGS AND PRECAUTIONS *(con't)*

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.

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ONCE-DAILY ORAL DOSING
IN ABSSSI OR CABP*

Dosage of NUZYRA Oral in ADULT ABSSSI patients

Treatment duration: 7 to 14 days[1]

Infection	Loading Doses	Maintenance Dose
Acute Bacterial Skin and Skin Structure Infections (ABSSSI)	**Day 1 and Day 2:** 450 mg orally ONCE-DAILY	300 mg orally ONCE-DAILY

NUZYRA 450 mg
PO QD x 2 days

THEN

NUZYRA 300 mg
PO QD
7-14 days total

For illustrative purposes only.
PO=per os; QD=once a day.

DOSAGE OF NUZYRA ORAL IN ADULT CABP PATIENTS

Treatment duration: 7 to 14 days[1]

Infection	Loading Doses	Maintenance Dose
Community Acquired Bacteria Pneumonia (CABP)*	**Day 1:** 300 mg orally TWICE	300 mg orally ONCE-DAILY

NUZYRA 300 mg
PO BID x 1 day

THEN

NUZYRA 300 mg
PO QD
7-14 days total

For illustrative purposes only.
BID=twice a day

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.

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

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.

once-daily
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IMPORTANT CONSIDERATIONS WHEN PRESCRIBING NUZYRA

Discharge on NUZYRA oral[1]

Tablet shown at actual size.

Instruct patients to:

- Fast for at least 4 hours and then take with water
  - NUZYRA can be taken at bedtime or upon waking
- Have nothing to eat or drink (except water) for 2 hours after dosing
- Not consume dairy products, antacids, or multivitamins for 4 hours after dosing
- Speak to their prescribing physician about the possibility of needing a dose adjustment if they are taking anticoagulant medication while also taking NUZYRA

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

We're here to help

Scan this code to locate a specialty pharmacy that carries NUZYRA tablets.

once-daily
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JUST 3 STEPS **TO PRESCRIBE**

NUZYRA Oral: Access via Specialty Pharmacy Network

1 PRESCRIBE

Send E-Rx with clinical notes and ICD-10 code to the pharmacy

NUZYRA Specialty Pharmacy Network includes*:

- CVS Specialty Pharmacy
- Kroger Specialty Pharmacy
- Walgreens Specialty Pharmacy
- Option Care Specialty Pharmacy
- PantherRx Specialty Pharmacy

2 NOTIFY PATIENT

Inform patients that the pharmacy will call them to review their insurance coverage

Instruct patients to speak with the pharmacy promptly to ensure that all of the necessary information is available to fill their NUZYRA prescription quickly

3 RECEIVE

Patients have 2 options for getting their NUZYRA prescription:

Delivered straight to their home at no extra charge. All pharmacies within the NUZYRA Specialty Pharmacy Network are able to provide same-day or next-day delivery

Picked up at a local CVS, Kroger, or Walgreens pharmacy

The majority of patients receive their prescription within 24 hours.[6]

*Paratek Pharmaceuticals, Inc. does not recommend or prefer the use of one pharmacy over another. NUZYRA Specialty Pharmacy Network as of 08/01/2022.

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.

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.

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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.

Please see accompanying full Prescribing Information.

References: 1. NUZYRA [Prescribing Information]. Paratek Pharmaceuticals, Inc. **2.** Honeyman L, Ismail M, Nelson ML, et al. Structure-activity relationship of the aminomethylcyclines and the discovery of omadacycline. *Antimicrob Agents Chemother*. 2015;59(11):7044-7053. **3.** Zhanel GG, Esquivel J, Zelenitsky, et al. Omadacycline: a novel oral and intravenous aminomethylcycline antibiotic agent. *Drugs*. 2020;80:285-313. **4.** Stets R, Popescu M, Gonong JR, et al. Omadacycline for community-acquired bacterial pneumonia. *N Engl J Med*. 2019;380(6):517-527. **5.** Bower J, Wright K, Burdette J. Prepared omadacycline for injection: nine-day stability and sterility in an elastomeric pump. *SAGE Open Med*. 2022;10:20503121221135568. doi: 10.1177/20503121221135568 **6.** Data on file. Paratek Pharmaceuticals, Inc.

SUPPORT FOR **YOUR PATIENTS**

THE MAJORITY OF ELIGIBLE PATIENTS **PAY AS LITTLE AS $15***

With the NUZYRA Copay Program, the majority of eligible commercially insured patients may pay as little as $15.*

*Terms and conditions apply.

Insurance coverage and reimbursement for NUZYRA are not guaranteed. Coverage and reimbursement depend on an individual patient's insurance plan. We recommend that you contact the insurance provider to verify NUZYRA coverage and reimbursement.

NUZYRA CENTRAL®

Questions? Call NUZYRA Central® Support Services at 1-877-4-NUZYRA (1-877-468-9972), Mon-Fri, 8 AM to 8 PM ET to speak with a representative.

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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PARATEK®

US-NUA-0673 01/23