once-daily

NUZYRA®

(omadacycline)

100 mg for injection / 150 mg tablets

IV ORDERING AND ADMINISTRATION GUIDE

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.

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

SPECIALTY DISTRIBUTOR NETWORK

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

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

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

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.

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

FOR INJECTION

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	$3450

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, 9 AM to 8 PM ET** to speak with a representative.

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.

Clostridium 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 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.

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DOSAGE REGIMEN

NUZYRA® (omadacycline) DOSAGE AND ADMINISTRATION

DOSAGE OF NUZYRA IN CABP AND ABSSSI ADULT PATIENTS TREATMENT DURATION: 7-14 DAYS		
INFECTION	**LOADING DOSES**	**MAINTENANCE DOSE**
CABP	Day 1: 200 mg by intravenous infusion over 60 minutes **OR** 100 mg by intravenous infusion over 30 minutes twice	100 mg by intravenous infusion over 30 minutes once daily **OR** 300 mg orally once daily
ABSSSI	Day 1: 200 mg by intravenous infusion over 60 minutes **OR** 100 mg by intravenous infusion over 30 minutes twice	100 mg by intravenous infusion over 30 minutes once daily **OR** 300 mg orally once daily
ABSSSI (NUZYRA tablets only)	Day 1 and Day 2: 450 mg orally once daily	300 mg orally once daily

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
- Alternative IV loading dose: 100 mg over 30 minutes, twice on Day 1

NUZYRA ORAL[1]

- Fast for at least 4 hours and then take with water
  —NUZYRA can be taken at bedtime or upon waking
- No food or drink (except water) for 2 hours after dosing
- No dairy products, antacids, or multivitamins for 4 hours after dosing
- Efficacy and safety of an oral loading dose was not evaluated in CABP

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

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.

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

IV PREPARATION

PREPARATION[1]

1. 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.
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 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 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 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 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[1]

PREPARATION OF NUZYRA IV INFUSION			
NUZYRA FOR INJECTION DOSE	NUMBER OF VIALS TO RECONSTITUTE FOR FURTHER DILUTION	VOLUME OF RECONSTITUTED SOLUTION (5 mL/VIAL) TO WITHDRAW FOR FURTHER DILUTION	FINAL INFUSION CONCENTRATION OF NUZYRA
200 mg	2 Vials	10 mL	2 mg/mL
100 mg	1 Vial	5 mL	1 mg/mL

IMPORTANT SAFETY INFORMATION (cont.)

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.

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STORAGE OF THE DILUTED INFUSION SOLUTION[1]

- If at room temperature (≤25°C), use within 12 hours
- If refrigerated (2°C to 8°C), use within 7 days
  —When refrigerated, remove infusion bag 60 minutes before use and incubate in a vertical position at room temperature
- Do not freeze

Vial is not actual size.

INFUSION INSTRUCTIONS (AFTER RECONSTITUTION AND DILUTION)[1]

- Loading Dose: Use a total intravenous infusion time of 60 minutes for a 200 mg dose
  —Note: There is an alternative IV loading dose for CABP and ABSSSI of 100 mg to be administered twice on Day 1 over a period of 30 minutes
- Once-Daily Maintenance Dose: Use a total intravenous 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 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 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F)
- Do not freeze

IMPORTANT SAFETY INFORMATION (cont.)

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.

To report SUSPECTED ADVERSE REACTIONS, contact Paratek Pharmaceuticals, Inc. at 1-833-727-2835 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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Reference: 1. NUZYRA [Prescribing Information]. Boston, MA: Paratek Pharmaceuticals, Inc.

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