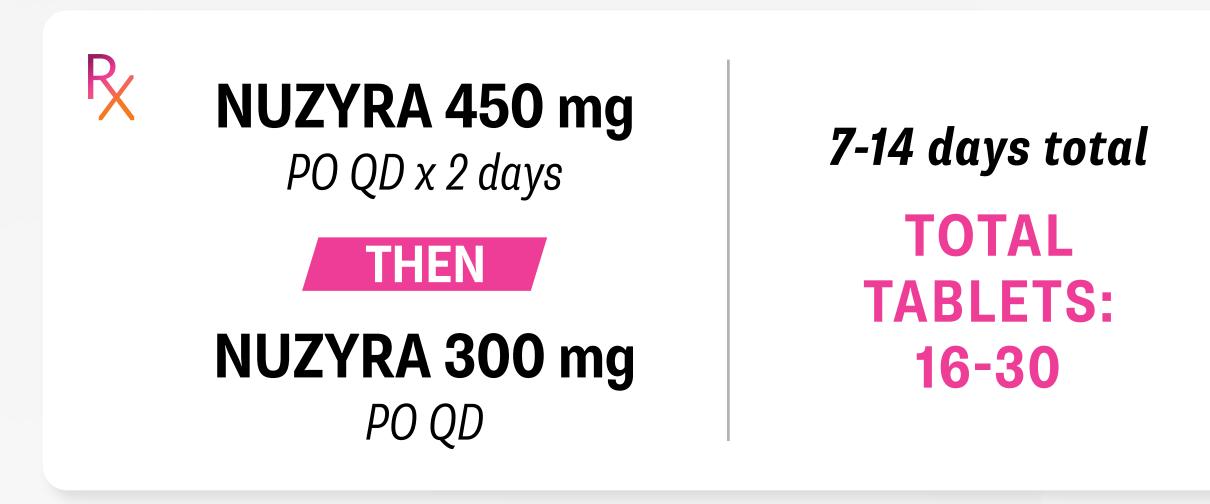
# NUZYRA<sup>®</sup> ORAL DOSING IN ABSSSI **ONCE-DAILY DOSING<sup>1</sup>:** Treatment duration: 7-14 days<sup>1</sup>

# **DAY 1-2: Loading Dose** 450 mg (3 tablets) once a day on Days 1 and 2

Tablets are not shown at actual size.

# **HOW TO PRESCRIBE**

50



# NUZYRA is available today at our network specialty pharmacies Visit <u>nuzyra.com/find</u>

### **INDICATION** and **USAGE**

**INDICATION:** NUZYRA<sup>®</sup> (omadacycline) is a tetracycline-class antibacterial indicated for the treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSI) in adults caused by certain susceptible microorganisms. See complete *Indications 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 <u>Important Safety Information</u> and full <u>Prescribing Information</u> at NUZYRA.com.



**Once-Daily** Maintenance Dose 300 mg (2 tablets)



## THE CURRENT SIS GUIDELINES FOR THE MANAGEMENT OF SSTIS<sup>2</sup>





100 mg for injection / 150 mg tablets

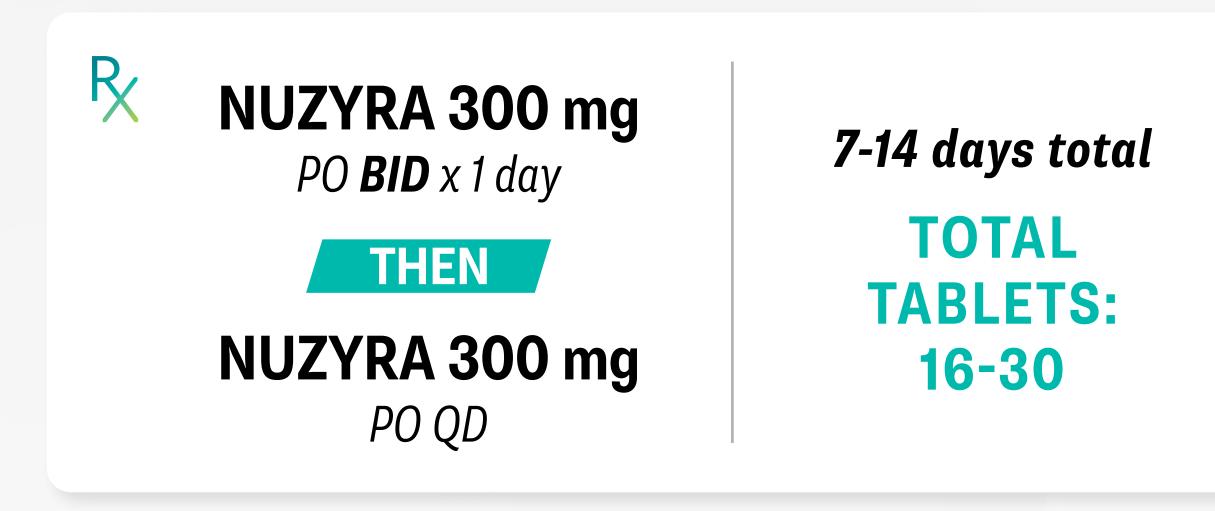
# NUZYRA<sup>®</sup> ORAL DOSING IN CABP **ONCE-DAILY DOSING<sup>1\*</sup>: Treatment duration: 7-14 days<sup>1</sup>**

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

\*For treatment of CABP, the oral loading dose is 300 mg twice on Day 1.<sup>1</sup>

# **HOW TO PRESCRIBE**

5



# **NUZYRA** is available today at our network specialty pharmacies Visit <u>nuzyra.com/find</u>

### **INDICATION** and **USAGE**

**INDICATION:** NUZYRA<sup>®</sup> (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 *Indications 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.

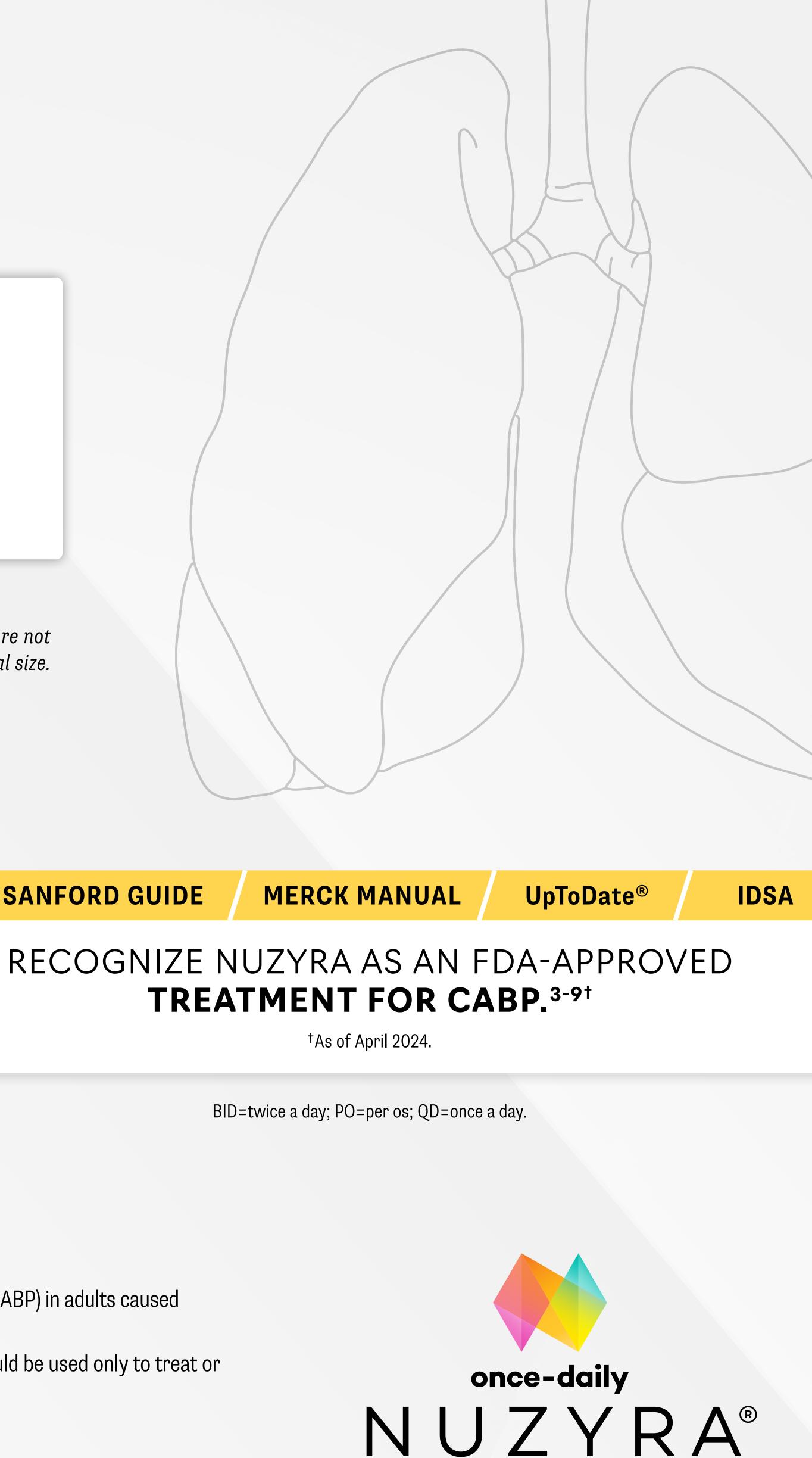
Please see <u>Important Safety Information</u> and full <u>Prescribing Information</u> at NUZYRA.com.

**Once-Daily Maintenance Dose** 300 mg (2 tablets)



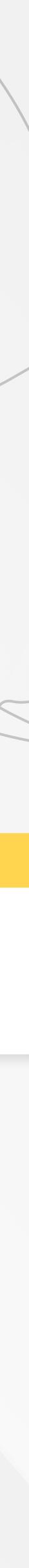
Tablets are not shown at actual size.

**THE SANFORD GUIDE** 



(omadacycline)

100 mg for injection / 150 mg tablets



# WHEN PRESCRIBING ORAL NUZYRA FOR CABP AND ABSSSI, INSTRUCT PATIENTS TO<sup>1</sup>:



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

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.<sup>1</sup>**

# **NUZYRA** is also available in an intravenous (IV) formulation<sup>1</sup>

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



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



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



100 mg for injection / 150 mg tablets

# **INDICATIONS and USAGE**

**INDICATIONS:** NUZYRA<sup>®</sup> (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.

References: 1. NUZYRA [Prescribing Information]. Paratek Pharmaceuticals, Inc. 2. Duane TM, Huston JM, Collom M, et al. Surgical Infection Society 2020 Updated Guidelines on the management of complicated skin and soft tissue infections. Surg Infect (Larchmt). 2021;22(4):383-399. 3. Sanford Guide. Pneumonia, community-acquired, adult, out-patient. Accessed May 10, 2023. https://webedition.sanford-guide.com/en/s patient. Accessed May 10, 2023. https://webedition.sanford-guide.com/en/sanford-guide-online/disease-clinical-condition/pneumonia-community-acquired 5. Merck Manuals Professional Edition. Community-Acquired Pneumonia. Accessed April 8, 2024. https://www.merckmanuals. com/professional/pulmonary-disorders/pneumonia/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 7. UpToDate®. Treatment of community-acquired pneumonia in adults who require hospitalization. Accessed October 6, 2023. https://sso.uptodate.com/contents/treatment-ofcommunity-acquired-pneumonia-in-adults-who-require-hospitalization 8. UpToDate®. Treatment of community-acquired pneumonia-inadults-in-the-outpatient-setting 9. Infectious Diseases Society of America (IDSA). CAP clinical pathway. Accessed April 8, 2024. https://www.idsociety.org/globalassets/idsa/practice-guidelines/community-acquired-pneumonia-in-adults/cap-clinical-pathway-final-online.pdf



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US-NUA-0647-02 04/25

Please see full **<u>Prescribing Information</u>** at NUZYRA.com.

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  $\geq 2\%$ ) are nausea, vomiting, infusion site reactions, alanine aminotransferase increased, aspartate aminotransferase increased, gamma-glutamy 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.



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