Omadacycline

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Abstract

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Keywords

Anti-infectives, Drug Information, Formulary Management / P & T

Generic Name: Omadacycline

Proprietary Name: *Nuzrya* (Paratek Pharmaceuticals)

Approval Rating: 1P

Therapeutic Class: Antibiotics, Tetracycline Derivatives

Similar Drugs: Minocycline

Sound-/Look-Alike Names: Minocycline, Tigecycline

Indications

Omadacycline is approved for the treatment of adults with acute bacterial skin and skin structure infections (ABSSSIs) and for the treatment of adults with community-acquired bacterial pneumonia (CABP).¹ Omadacycline should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. Susceptible microorganisms isolated in the CABP studies included *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydophila pneumoniae*. Susceptible microorganisms in the ABSSI studies included *S aureus* (methicillin-susceptible and methicillin-resistant isolates), *Staphylococcus lugdunensis*, *Streptococcus pyogenes*, *Streptococcus anginosus* group (includes *S anginosus*, *Staphylococcus intermedius*, and *Streptococcus constellatus*), *Enterococcus faecalis*, *Enterobacter cloacae*, and *Klebsiella pneumoniae*.¹

Other potential uses of omadacycline include the treatment of complicated and uncomplicated urinary tract infections (UTIs) and the treatment of various pathogenic agents (eg, anthrax, plague).^{2,3}

Clinical Pharmacology

Omadacycline is a semisynthetic derivative of minocycline and is classified as an aminomethylcycline within the

tetracycline class of antibacterial drugs.^{1,4} Similar to tetracyclines, omadacycline is a protein synthesis inhibitor that binds to 30S ribosomal subunits in the messenger RNA (mRNA) translation complex of bacteria and inhibits the binding of aminoacyl-transfer RNA (tRNA) to the mRNA-ribosome complex.^{1,4,5}

In vitro bactericidal activity of omadacycline was observed against streptococci, *Moraxella catarrhalis*, and *H influenzae*, while bacteriostatic activity was observed against enterococci, *S aureus*, and *Escherichia coli*.⁶

The chemical structure of omadacycline contains a unique alkylaminomethyl side chain at the C9 position of the tetracycline D ring (core 6-member ring) that enhances in vitro antibacterial activity against drug-resistant isolates, including strains expressing resistance through mechanisms of efflux and ribosomal protection.⁴⁻⁸ Omadacycline differs from the glycylcycline tetracyclines, tigecycline and eravacycline, by the presence of an aminomethyl group at the C9 position; this modification results in improved antimicrobial potency for these new-generation tetracyclines, attributed to stability to ribosomal protection proteins and efflux pump mechanisms.^{6,8}

In vitro, omadacycline has antimicrobial activity against Gram-positive, Gram-negative, anaerobic, and atypical pathogens. This includes better coverage against methicillin-resistant *S aureus* (MRSA) strains, penicillin- and multidrug-resistant *S pneumoniae* strains, and vancomycin-resistant

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Enterococcus compared with other tetracycline antimicrobials. Omadacycline also has good activity against *H influenzae*, *M catarrhalis*, atypical pathogens (including *M pneumoniae*, *L pneumophila*, and *C pneumoniae*), Enterobacteriaceae, *Ureaplasma* spp., *Bacillus anthracis*, *Yersinia pestis*, and *Clostridium difficile*.^{6,7,9-20}

Postantibiotic effect of omadacycline is similar to that of tigecycline, with the exception of enterococci (for which the postantibiotic effect was slightly longer with tigecycline), and better than linezolid.⁶

In vitro studies have not demonstrated antagonism between omadacycline and other commonly used antibacterials (eg, ampicillin, ceftazidime, ceftriaxone, daptomycin, gentamicin, imipenem, linezolid, piperacillin/tazobactam, vancomycin).¹

Pharmacokinetics

Peak plasma concentrations (C_{max}) occur shortly after intravenous (IV) infusion or within 3 hours after oral administration of omadacycline 300, 450, and 600 mg.^{6,7,21-23} C_{max} and area under the curve (AUC) increased with increasing doses, but in a less than dose-proportional manner.^{7,23} The bioavailability of the oral formulation is 34.5% relative to IV administration; the omadacycline 300 mg oral formulation produces a total exposure equivalent to omadacycline 100 mg IV.^{1,6,22}

Administration in the fasted state is recommended because oral bioavailability is decreased when administered within 2 to 4 hours of high-fat, nondairy food. The bioavailability is decreased by 15% to 17% by a nondairy meal 4 hours before dosing, 40% to 42% by a nondairy meal 2 hours before dosing, and 59% to 63% for a dairy meal 2 hours before dosing.^{1,7,23} Area under the curve was unaffected by age, but may be increased in females; however, no adjustment in dose based on gender is required.²⁴

Mean terminal half-life of omadacycline was about 13.5 hours on day 1 and about 17 hours on day 5. Steady-state levels were achieved by day 5 following daily oral administration.^{6,7} No enzymatically formed metabolites were identified.^{6,21} The volume of distribution was 333 to 640 L, and protein binding was 21%.⁶

In a pharmacokinetic study comparing omadacycline with tigecycline, healthy subjects were administered omadacycline 100 mg IV every 12 hours the first day and 100 mg IV every 24 hours the next 3 days, or tigecycline 100 mg IV for the first dose and then 50 mg IV every 12 hours for 6 doses. Following the start of the fifth dose of omadacycline, AUC_{0-24} (based on mean concentrations) in epithelial lining fluid and the ratio of the epithelial lining fluid to total plasma omadacycline concentration based on AUC_{0-24} values were 17.2 mg h/L and 1.47, respectively. The AUC_{0-24} value in alveolar cells was 302.5 mg h/L, and the ratio of the alveolar cells to total plasma omadacycline concentration was 25.8. The values of AUC_{0-12} based on mean concentrations of tigecycline in epithelial lining fluid and alveolar cells were 3.16 and 38.5 mg h/L, respectively. The ratio of the epithelial lining fluid and alveolar cells to total plasma concentrations of tigecycline

based on AUC_{0-12} values were 1.71 and 20.8, respectively.^{1,4} Epithelial lining fluid incorporation for both drugs is best characterized using linear 3- and 2-compartment models, and both drugs have similar epithelial lining fluid penetration.²⁵

No clinically significant differences in omadacycline pharmacokinetics were observed based on age, gender, race, or weight.¹ No clinically meaningful changes in the pharmacokinetics of omadacycline occurred in patients with impaired renal function or on the day of dialysis in patients with end-stage renal disease (ESRD) compared with healthy subjects.^{1,26}

Comparative Efficacy

Indication: ABSSSIs

Guidelines

Guideline: Practice guidelines for the diagnosis and management of skin and soft tissue infections: 2014 update by the Infectious Diseases Society of America

Reference: Infectious Diseases Society of America, 2014²⁷

Comments: Management strategies are based on clinical presentation, diagnosis, and pathogens. The guidelines have not been updated since 2014 and do not include several new antibiotics that have been approved for the treatment of ABSSSI.

Studies

Drug: Omadacycline vs Linezolid

Reference: Montravers, et al, 2018 (OASIS-1 trial)^{1,28-31}

Study Design: Phase 3, randomized, double-blind, multicenter study

Study Funding: Paratek Pharmaceuticals

Patients: A total of 655 adults with ABSSSI. Patients had cellulitis (38%), wound infection (33%), and major abscess (29%). Mean patient age was 47 years; 65% were male; 92% were white; and mean body mass index (BMI) was 28.1 kg/m².

Intervention: Patients were randomized (1:1) to omadacycline (100 mg IV twice daily for 2 doses, then 100 mg IV once daily) or to linezolid (600 mg IV twice daily). Patients in both study arms were treated for 7 to 14 days. Intravenous therapy could be switched to oral therapy (omadacycline 300 mg once daily or linezolid 600 mg twice daily) after a minimum of 3 days.

Results

Primary End Point(s)

- Early clinical response (at least 20% reduction in lesion size at 48-72 hours after the first dose) (Food and Drug Administration [FDA] primary end point) occurred in 84.8% of patients with omadacycline and 85.5% with linezolid (treatment difference: -0.7; 95% confidence interval [CI]: -6.3 to 4.9) in the modified intention-to-treat (mITT) population (patients without

a potentially causative monomicrobial Gram-negative infection).

- Clinical success (survival with resolution of symptoms per investigator assessment) at the posttreatment evaluation visit (7-14 days after completion of therapy) (European Medicines Agency [EMA] primary end point) was achieved in 86.1% of patients with omadacycline and 83.6% with linezolid (treatment difference: 2.5; 95% CI: -3.2 to 8.2) in the mITT population and 96.3% and 93.5%, respectively, in the clinically evaluable population.

Secondary End Point(s)

- Success rate in *S aureus*, MRSA, *S anginosus*, and mixed infections was similar for omadacycline and linezolid in the microbiologically mITT population.

Other End Point(s)

- Subgroup analysis of patients with chronic kidney disease, higher BMI, IV drug use history, and hepatitis C showed no differences in efficacy outcomes or safety. Omadacycline may have higher clinical success in patients with type 2 diabetes.^{28,31}

Comments: Results are similar to the previous phase 2 study that compared the same 2 drugs in patients with complicated skin and skin structure infections.³²

Limitations: Results data are available only in press releases, meeting abstracts, posters, a review summarizing findings in the development of omadacycline, and the prescribing information.

Reference: Montravers, et al, 2018 (OASIS-2 trial)^{1,30,33,34}

Study Design: Phase 3, randomized, double-blind, multicenter study

Study Funding: Paratek Pharmaceuticals

Patients: A total of 735 adults (18 years and older) with ABSSSI. Patients were excluded if they had significant immunological disease, severe renal disease or need for dialysis, evidence of septic shock, or a history of hypersensitivity or allergic reaction to any tetracycline or to linezolid. Patients had wound infections (58%), cellulitis (24%), and major abscess (18%). Mean patient age was 44 years; 63% were male; 91% were white; and mean BMI was 27.9 kg/m².

Intervention: Patients were randomized to treatment with omadacycline (450 mg orally once daily on days 1 and 2, followed by 300 mg orally once daily) or to linezolid (600 mg orally twice daily) for 7 to 14 days.

Results

Primary End Point(s)

- Early clinical response (survival with at least 20% reduction of lesion size 48-72 hours after the first dose

was administered) (FDA-specified primary end point) occurred in 87.3% of patients with omadacycline and 82.2% with linezolid (treatment difference: 5.1; 95% CI: -0.2 to 10.5).

- Clinical success (survival with resolution of signs and symptoms per investigator assessment) at posttreatment evaluation (7-14 days after completion of therapy) (EMA-specified primary end point) was achieved in 83.9% patients with omadacycline and 80.5% with linezolid in the mITT population (treatment difference: 3.4; 95% CI: -2.3 to 9.1) and 97.9% and 95.5%, respectively, in the clinically evaluable population.

Comments: Omadacycline met the primary FDA and EMA efficacy end points of noninferiority in the mITT population (10% noninferiority margin, 95% CI) compared with linezolid for early clinical response and the posttreatment evaluation.

Limitations: Results data are available only in press releases, meeting abstracts, a review summarizing findings in the development of omadacycline, and the prescribing information.

Indication: CABP

Guidelines

Guideline: Infectious Disease Society of America/American Thoracic Society consensus guidelines on the management of community-acquired pneumonia in adults

Reference: Infectious Disease Society of America/American Thoracic Society, 2007³⁵

Comments: Management strategies are based on clinical presentation, diagnosis, and pathogens. Initial therapy may require the use of IV antibiotics, followed by a switch to an oral formulation of the same antibiotic or same pharmacological class when the patient's medical condition has stabilized (eg, temperature less than 37.8°C [100.04°F], heart rate is 100 beats per minute or less, respiratory rate is 24 breaths per minute or less, systolic blood pressure is 90 mm Hg or higher, arterial oxygen saturation is 90% or higher or oxygen partial pressure is 60 mm Hg or higher on room air, normal mental status), including noted clinical improvement and ability to maintain oral intake. The guidelines have not been updated since 2007 and do not include several new antibiotics that have been approved for the treatment of community-acquired pneumonia.

Studies

Drug: Omadacycline vs Moxifloxacin

Reference: Stets R, et al, 2017 (OPTIC study)^{36,37}

Study Design: Phase 3, randomized, double-blind, multicenter noninferiority study

Study Funding: Paratek Pharmaceuticals

Patients: A total of 774 adults (18 years and older) with CABP. Patients were excluded if they had known or suspected hospital-acquired pneumonia, evidence of significant immunological disease, history of hypersensitivity, or allergic reaction to any tetracycline or any fluoroquinolone antibiotic. Median age was 62 years, and 20.4% were older than 75 years.

Intervention: Patients were randomized to treatment with omadacycline 100 mg IV every 12 hours for 2 doses, then 100 mg IV once daily, or moxifloxacin 400 mg IV once daily. After a minimum of 3 days of IV therapy, patients could be switched to oral therapy (omadacycline 300 mg once daily or moxifloxacin 400 mg every 12 hours) for a total treatment duration of 7 to 14 days.

Results

Primary End Point(s)

- Early clinical response (defined as survival, no receipt of rescue antibacterial therapy, and improvement in at least 2 of 4 subject symptoms [cough, sputum production, pleuritic chest pain, dyspnea] without deterioration in any of these 4 symptoms at 72-120 hours after first dose) occurred in 81.1% of patients with omadacycline and 82.7% with moxifloxacin (risk difference [RD]: -1.6; 95% CI: -7.1 to 3.8).
- Clinical success (per investigator assessment and defined as survival with resolution of signs and symptoms of the infection to the extent that further antibacterial therapy was not necessary) at posttreatment evaluation (5-10 days after last dose) was achieved in 87.6% of patients with omadacycline and 85.1% with moxifloxacin (RD: 2.5; 95% CI: -2.4 to 7.4).

Secondary End Point(s)

- Clinical success at posttreatment evaluation in the clinically evaluable cohort was 92.9% with omadacycline and 90.4% with moxifloxacin (RD: 2.5; 95% CI: -1.7 to 6.8).

Comments: The prevalence and resistance profiles of baseline pathogens were similar between the 2 groups. The minimum inhibitory concentration of the isolated organism did not influence the clinical outcome. Eight patients in the omadacycline group had tetracycline-resistant *S pneumoniae*, and all 8 patients responded to omadacycline therapy.³⁸ The study was conducted in Belgium, Brazil, Bulgaria, Croatia, Czechia, Georgia, Germany, Greece, Hungary, Israel, the Republic of Korea, Latvia, Mexico, Peru, Philippines, Poland, Romania, the Russian Federation, Slovakia, South Africa, Spain, Taiwan, Turkey, Ukraine, and the United States.

Limitations: Results data are limited to meeting abstracts and the prescribing information.

Contraindications, Warnings, and Precautions

Contraindications

Omadacycline is contraindicated in patients with known hypersensitivity to the drug or tetracycline class antibacterial drugs, or to any of product excipients (injectable: sucrose; tablet: colloidal silicon dioxide, crospovidone, glycerol monocaprylocaprate, iron oxide yellow, lactose monohydrate, microcrystalline cellulose, polyvinyl alcohol, sodium bisulfite, sodium lauryl sulfate, sodium stearyl fumarate, talc, and titanium dioxide).¹

Warnings and Precautions

In clinical trials evaluating use in CABP, there was an imbalance of mortality between the 2 treatment groups; death occurred in 2% of the omadacycline group and 1% of the moxifloxacin group. The reason for the mortality imbalance is unknown.¹

Tooth discoloration (eg, yellow-gray-brown) and enamel hypoplasia can occur if omadacycline is used during tooth development (last half of pregnancy, in infancy, and in childhood [up to 8 years of age]) and may be permanent.¹

Reversible inhibition of bone growth may occur if used during the second and third trimesters of pregnancy, in infancy, and in childhood (up to 8 years of age). The effect on bone growth is reversible when omadacycline therapy is discontinued.¹

Hypersensitivity reactions, including life-threatening hypersensitivity (anaphylactic) reactions, may occur during omadacycline therapy or in patients with a history of hypersensitivity to tetracycline class antibacterial drugs. Therefore, omadacycline is contraindicated in patients with known hypersensitivity to tetracycline class antibacterial drugs.¹

Clostridium difficile-associated diarrhea (CDAD) may occur during or after omadacycline therapy. The CDAD should be considered in any patient who presents with diarrhea following omadacycline therapy. If CDAD is suspected or confirmed, appropriate therapy should be implemented.¹

Other adverse reactions that may be associated with tetracycline class antibacterial drugs include photosensitivity, pseudotumor cerebri, and antianabolic action, which led to increased serum urea nitrogen, azotemia, acidosis, hyperphosphatemia, pancreatitis, and abnormal liver function tests.¹

There are no adequate and well-controlled studies of omadacycline in pregnant women. Tetracycline class antibacterial drugs, including omadacycline, may cause discoloration of deciduous teeth and reversible inhibition of bone growth when administered during the second and third trimesters of pregnancy. The limited data regarding the safety of omadacycline use during pregnancy are insufficient to inform drug-associated risks.¹

No studies have been conducted to assess the presence of omadacycline in human milk or its effects on breastfeeding.

Table 1. Adverse Reactions (Incidence $\geq 2\%$) in Patients With CABP Treated With Omadacycline in the OPTIC Trial.¹

Adverse reaction	Omadacycline (n = 382)	Moxifloxacin (n = 388)
ALT increased	3.7%	4.6%
Hypertension	3.4%	2.8%
Gamma-glutamyltransferase increased	2.6%	2.1%
Insomnia	2.6%	2.1%
Vomiting	2.6%	1.5%
Constipation	2.4%	1.5%
Nausea	2.4%	5.4%
AST increased	2.1%	3.6%
Headache	2.1%	1.3%

Note. CABP = community-acquired bacterial pneumonia; ALT = alanine aminotransferase; AST = aspartate aminotransferase.

infants or milk production. Because of the potential for serious adverse reactions, including tooth discoloration and inhibition of bone growth, breastfeeding is not recommended during treatment with omadacycline and for 4 days after the last dose.¹

Safety and efficacy of omadacycline have not been established in pediatric patients younger than 18 years.¹

Adverse Reactions

The most common adverse reactions associated with omadacycline therapy included nausea, vomiting, infusion-site reactions, alanine aminotransferase (ALT) increased, aspartate aminotransferase (AST) increased, gamma-glutamyltransferase increased, hypertension, headache, diarrhea, insomnia, and constipation (see Tables 1 and 2).^{1,30,33}

Omadacycline may increase heart rate (antagonism of muscarinic receptor) but has a low potential for inducing cardiac arrhythmia or clinically significant cardiovascular toxicity. Observed increases in heart rate tended to decline over time and did not reach clinical significance, nor were clinically meaningful changes in blood pressure or electrocardiogram observed in clinical studies.³⁹⁻⁴¹

Drug Interactions

Omadacycline does not induce or inhibit cytochrome P450 (CYP-450) isozymes. There was no time-dependent inhibition of omadacycline or its possible metabolites for CYP1A1, 1A2, 2A6, 2B6, 2C8, 2C9, 2C19, 2D6, 3A4/5, or UGT1A1. Omadacycline does not inhibit P-glycoprotein (P-gp), breast cancer resistance protein (BCRP), multidrug resistance-associated protein 2 (MRP-2), OATP1B1, and OATP1B3, nor does it induce P-gp or MRP-2 mRNA. Omadacycline is a weak substrate for P-gp (but not MRP-2 or BCRP), but is not an inhibitor or an inducer of P-gp, MRP-2, or BCRP.^{1,6,21}

Anticoagulant therapy may need to be adjusted during omadacycline therapy; tetracycline antimicrobials can depress plasma prothrombin activity. The dose of the anticoagulant may need to be decreased during omadacycline therapy.¹

Absorption may be impaired by antacids containing aluminum, calcium, or magnesium; bismuth subsalicylate; and iron-containing preparations.¹

Recommended Monitoring

If diarrhea occurs, CDAD should be considered.¹

Dosing

Omadacycline can be given by IV or oral administration.¹ The recommended dosing for the treatment of ABSSSI and for the treatment of CABP is provided in Tables 3 and 4.¹

Omadacycline must be reconstituted and further diluted under aseptic conditions. Each 100 mg vial should be reconstituted with 5 mL of sterile water for injection; then gently swirl the contents and let the vial stand until the cake is completely dissolved and any foam disperses. The vial should not be shaken. The reconstituted solution should be withdrawn from the vial within 1 hour and further diluted with 100 mL (nominal volume) of sodium chloride 0.9% injection or dextrose 5% injection in an IV bag for injection. The final diluted solution should be 1 or 2 mg/mL.¹

Administer omadacycline IV through a dedicated line or through a Y-site. The IV solution should not be mixed or given with any solution containing multivalent cations (eg, calcium, magnesium). Coinfusion with other medications has not been studied. If the same IV line is used for sequential infusion of drugs or solutions, it should be flushed with sodium chloride 0.9% injection or dextrose 5% injection before and after infusion of omadacycline.¹

Oral omadacycline should be administered in the fasted state (at least 4 hours) and taken with water. After oral dosing, no food or drink (except water) should be consumed for 2 hours, and dairy products, antacids, and multivitamins should be avoided for at least 4 hours.^{1,23}

No dosage adjustment is required for adults with impaired renal or hepatic function, or on the day of dialysis in patients with ESRD.^{1,26}

Product Availability

The New Drug Application (NDA) for omadacycline was submitted in February 2018.² The NDA was accepted for priority review in April 2018. The materials for marketing approval in the European Union will be submitted in the second half of 2018.² Omadacycline was previously granted “qualified infectious disease product” designation and “fast track” status by the FDA for target indications of ABSSSI, CABP, and uncomplicated and complicated UTIs.^{2,42} The

Table 2. Adverse Reactions (Incidence $\geq 2\%$) in Patients With ABSSSI Treated With Omadacycline in Pooled OASIS-1 and OASIS-2 Trials.¹

Adverse reaction	Omadacycline (n = 691)	Linezolid (n = 689)
Nausea	21.9%	8.7%
Vomiting	11.4%	3.9%
Infusion-site reactions	5.2%	3.6%
ALT increased	4.1%	3.6%
AST increased	3.6%	3.5%
Headache	3.3%	3%
Diarrhea	3.2%	2.9%

Note. ABSSSI = acute bacterial skin and skin structure infections; ALT = alanine aminotransferase; AST = aspartate aminotransferase.

Table 3. Omadacycline Dosing in Adults With Acute Bacterial Skin and Skin Structure Infections.¹

Loading doses	Maintenance dose	Treatment duration
200 mg by IV infusion over 60 min on day 1 Or 100 mg by IV infusion over 30 min, twice on day 1	100 mg by IV infusion over 30 min once daily Or 300 mg orally once daily	7 to 14 days
450 mg orally once daily on days 1 and 2	300 mg orally once daily	

Table 4. Omadacycline Dosing Recommendations in Adults With Community-Acquired Bacterial Pneumonia.¹

Loading doses	Maintenance dose	Treatment duration
200 mg by IV infusion over 60 min on day 1 Or 100 mg by IV infusion over 30 min, twice on day 1	100 mg by IV infusion over 30 min once daily Or 300 mg orally once daily	7 to 14 days

FDA Antimicrobials Drug Advisory Committee voted for approval of omadacycline for the treatment of ABSSSI (17-1) and CABP (14-4).⁴³ Omadacycline was approved in October 2018.⁴⁴

The IV formulation consists of a single-dose vial containing omadacycline 100 mg (equivalent to omadacycline tosylate 131 mg), which must be reconstituted and further diluted prior to IV administration. Each film-coated tablet contains omadacycline 150 mg (equivalent to omadacycline tosylate 196 mg).¹

Both omadacycline formulations should be stored at 20°C to 25°C (68°F-77°F); excursions are permitted to 15°C to 30°C (59°F-86°F). Do not freeze.¹

Omadacycline diluted infusion solution may be used within 24 hours if stored at room temperature (less than or equal to 25°C) or within 48 hours when refrigerated (2°C-8°C [36°F-46°F]). When storing the infusion solution in the refrigerator, the infusion bag should be removed from the refrigerator and incubated in a vertical position at room temperature 60 minutes before use. Do not freeze.¹

Drug Safety/Risk Evaluation and Mitigation Strategy (REMS)

No REMS is required for omadacycline.⁴⁴

Conclusion

Omadacycline, an aminomethylcycline, is FDA approved for the treatment of adults with ABSSSI or CABP. Omadacycline is available as an IV and oral formulation. Its clinical development was supported by 3 pivotal registration studies, 2 studies evaluating its efficacy in the treatment of ABSSSI and 1 study evaluating its efficacy in the treatment of CABP. Its safety profile appears similar to other tetracycline antibiotics.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

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