Orbactiv® (oritavancin) for injection 1200 mg

Kimyrsa™ (oritavancin) for injection 1,200 mg

ORBACTIV® and KIMYRSA®: Two effective ABSSSI* treatments for patient care in any setting

The power of oritavancin can benefit your patients and help reduce healthcare burden

*INDICATION AND USAGE

Both KIMYRSA® and ORBACTIV® are oritavancin products that are indicated for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused or suspected to be caused by susceptible isolates of the following gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-susceptible [MSSA] and methicillin-resistant [MRSA] isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus anginosus* group (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), and *Enterococcus faecalis* (vancomycin-susceptible isolates only).

To reduce the development of drug-resistant bacteria and maintain the effectiveness of oritavancin and other antibacterial drugs, oritavancin should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

KIMYRSA® and ORBACTIV® are not approved for combination use and have differences in dose strength, duration of infusion, and preparation instructions, including reconstitution and dilution instructions and compatible diluents. Please see the full Prescribing Information for each product.

IMPORTANT SAFETY INFORMATION

Contraindications

Use of intravenous unfractionated heparin sodium is contraindicated for 120 hours (5 days) after oritavancin administration because the activated partial thromboplastin time (aPTT) test results may remain falsely elevated for approximately 120 hours (5 days) after oritavancin administration.

Oritavancin products are contraindicated in patients with known hypersensitivity to oritavancin.

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

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Oritavancin simplifies and streamlines ABSSSI treatment

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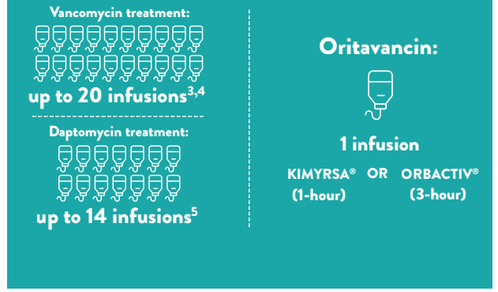
Kimyrsa™ (oritavancin) for injection 1,200 mg

Oritavancin is administered as a single 1,200-mg infusion[1,2]



- Administration in **multiple care settings**, with no hospital stay required[6]
- **Freedom** from PICC lines[7]
- **No dosing adjustments** based on age, weight, or mild-to-moderate renal or hepatic impairment[1,2]
- **A full course of therapy in a single dose** ensures adherence, which can improve outcomes[1,2,7]

The triple MOA of oritavancin leads to more rapid bactericidal activity in vitro[8]*

Other commonly prescribed antibiotics for ABSSSI rely mainly on a single MOA*

	Transpeptidation	Transglycosylation	Disrupts bacterial membrane integrity
KIMYRSA[1]	✓	✓	✓
ORBACTIV[2]	✓	✓	✓
Dalbavancin[9]	✓		
Vancomycin[10,11]		✓	
Daptomycin[5]			✓

- Killing of MRSA isolate (ATCC 43300) by oritavancin was rapid, with bactericidal activity **within 1 hour**[8†]
- In contrast, the bactericidal activities of dalbavancin and vancomycin occurred more slowly over a 24-hour period[8†]

***In vitro activity does not necessarily correlate to clinical efficacy.**
†Bactericidal activity defined as a ≥3-log reduction in bacterial viability at 24 hours (or earlier, as indicated), relative to the starting inoculum.[8]

ABSSSI, acute bacterial skin and skin structure infections; PICC, peripherally inserted central catheter; MOA, mechanism of action; MRSA, methicillin-resistant Staphylococcus aureus.

Important Safety Information (cont)

Warnings and Precautions

Coagulation test interference: Oritavancin has been shown to artificially prolong aPTT for up to 120 hours, and may prolong PT and INR for up to 12 hours and ACT for up to 24 hours. Oritavancin has also been shown to elevate D-dimer concentrations up to 72 hours. For patients who require aPTT monitoring within 120 hours of oritavancin dosing, consider a non-phospholipid dependent coagulation test such as a Factor Xa (chromogenic) assay or an alternative anticoagulant not requiring aPTT.

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

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Consider ORBACTIV® (oritavancin) for INPATIENT TREATMENT*

Orbactiv® (oritavancin) for injection 1200 mg

Established efficacy and safety for the treatment of ABSSSI[2†]

- 3-hour infusion
- Dilution in 5% dextrose in water
- Administered as a 1,000-mL infusion

Real-world evidence demonstrates patient and healthcare benefits of ORBACTIV inpatient treatment:

Shorten hospital stays[12‡]

- Utilizing ORBACTIV to expedite hospital discharge post receipt of IV vancomycin led to a 2.1-day reduction in hospital length of stay (LOS) compared to step-down oral antibiotics

Reduce readmissions[13§]

- Only 2.6% of patients who received ORBACTIV in the inpatient setting to facilitate hospital discharge experienced an infection-related readmission within 30 days

Broad insurance coverage[14‖]

- 98% drug coverage across commercial and government payers

Due to their nature, retrospective studies can contain material limitations and their results should be considered in light of the entire body of available evidence, including clinical trial data.

*All treatment and clinical pathway decisions, including the best setting of care for administering treatment to a given patient, should be made in the best clinical interests of that patient and be based on the healthcare provider's independent analysis and evaluation. Whether a patient is treated in the inpatient or outpatient setting of care is a clinical decision that is based on the medical judgment of their healthcare provider.

†The efficacy and safety of ORBACTIV has been established from adequate and well-controlled trials in patients with ABSSSI. In the SOLO I and SOLO II trials, the early clinical response rates at 48-72 hours for patients receiving ORBACTIV were 82.3% and 80.1%, respectively. Additionally, clinical success rates at 14-24 days for patients receiving ORBACTIV were 79.6% and 82.7%, respectively. Please see full Prescribing Information for details.[1,2]

‡Results from a real-world, retrospective, descriptive cohort study of 199 patients.[12]

§Results from a multicenter, retrospective chart review of 151 patients.[13]

‖Coverage based on 95 claims from 1/1/2024-12/23/2024, excluding facility and provider out of network claims.[14]

IV, intravenous.

Important Safety Information (cont)

Warnings and Precautions (cont)

Serious hypersensitivity reactions, including anaphylaxis, have been reported with the use of oritavancin products. Discontinue infusion if signs of acute hypersensitivity occur. Closely monitor patients with known hypersensitivity to glycopeptides.

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Consider KIMYRSA® (oritavancin) for OUTPATIENT TREATMENT*†

Kimyrsa™ (oritavancin) for injection 1,200 mg

An advanced formulation of oritavancin with streamlined dosing and administration[1‡]:

- 1-hour infusion
- 1-vial preparation
- Dilution in 5% dextrose in water or 0.9% sodium chloride may benefit patients with dysglycemia[1,15]
- Administered as a low 250-mL infusion for patients with volume limitation[1,16]

Real-world evidence demonstrates patient and healthcare benefits of KIMYRSA outpatient treatment[§]:

Avoid inpatient admission[17‖]

- 97.9% (n=137/140) of patients avoided an inpatient admission when treated with KIMYRSA in the outpatient setting

Reduce 30-day readmission rates[18¶]

- Only 2.9% (n=4/140) of ABSSSI patients treated with KIMYRSA outpatient treatment were admitted to the hospital within 30 days of ED discharge

Broad insurance coverage[14#]

- 96% drug coverage across commercial and government payers

Due to their nature, retrospective studies can contain material limitations and their results should be considered in light of the entire body of available evidence, including clinical trial data.

*All treatment and clinical pathway decisions, including the best setting of care for administering treatment to a given patient, should be made in the best clinical interests of that patient and be based on the healthcare provider's independent analysis and evaluation. Whether a patient is treated in the inpatient or outpatient setting of care is a clinical decision that is based on the medical judgment of their healthcare provider.

†Outpatient settings include the ED/observation units, infusion centers, physician's offices, or patients' homes.

‡The efficacy and safety of KIMYRSA has been established from adequate and well-controlled trials of another oritavancin product, ORBACTIV, in patients with ABSSSI. In the SOLO I and SOLO II trials, the early clinical response rates at 48-72 hours for patients receiving ORBACTIV were 82.3% and 80.1%, respectively. Additionally, clinical success rates at 14-24 days for patients receiving ORBACTIV were 79.6% and 82.7%, respectively. Please see full Prescribing Information for details.[1,2]

§Results from a retrospective study of 140 patients who received KIMYRSA in the ED.[17,18]

‖2 out of the 3 admitted patients turned out not to be candidates for KIMYRSA per hospital protocol.[17]

¶Oritavancin protocol-compliant readmissions.[18]

#Coverage based on 578 claims from 1/1/2024-12/23/2024, excluding facility and provider out of network claims.[14]

ED, emergency department.

Important Safety Information (cont)

Warnings and Precautions (cont)

Infusion related reactions: Infusion reactions characterized by chest pain, back pain, chills and tremor have been observed with the use of oritavancin products, including after the administration of more than one dose of oritavancin during a single course of therapy. Stopping or slowing the infusion may result in cessation of these reactions.

Clostridioides difficile-associated diarrhea: Evaluate patients if diarrhea occurs.

Concomitant warfarin use: Oritavancin has been shown to artificially prolong PT/INR for up to 12 hours. Patients should be monitored for bleeding if concomitantly receiving oritavancin products and warfarin.

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Comprehensive Patient Support

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KIMYRSA® and ORBACTIV® both offer a support program that provides a single point of contact for all your patients' benefits, claims, and reimbursement support needs

- **Benefit verification**
- **Prior authorization support**
- **Coding and reimbursement information**
- **Claims appeals process support**
- **Research sources of alternate funding**
- **Copay savings program**
- **Patient assistance program**

For information about the Patient Support Program, call 1-844-546-9772
Monday-Friday
8:00 AM to 8:00 PM ET

References: 1. KIMYRSA. Package insert. Melinta Therapeutics; 2021. **2.** ORBACTIV. Package insert. Melinta Therapeutics; 2022. **3.** Corey GR, Arhin FF, Wikler MA, et al. Pooled analysis of single-dose oritavancin in the treatment of acute bacterial skin and skin-structure infections caused by Gram-positive pathogens, including a large patient subset with methicillin-resistant Staphylococcus aureus. *Int J Antimicrob Agents*. 2016;48(5):528-534. doi:10.1016/j.ijantimicag.2016.07.019 **4.** Vancomycin. Package Insert. ANI Pharmaceuticals Inc. **5.** Daptomycin. Package insert. Merck Sharp & Dohme LLC. **6.** Lodise T, Redell M, Armstrong S, Sulham K, Corey G. Efficacy and safety of oritavancin relative to vancomycin for patients with acute bacterial skin and skin structure infections (ABSSSI) in the outpatient setting: results from the SOLO clinical trials. *Open Forum Infect Dis*. 2017;4(1):ofw274. doi:10.1093/ofid/ofw274 **7.** Dretske D, Schulz L, Werner E, Sharp B, Pulia M. Effectiveness of oritavancin for management of skin and soft tissue infections in the emergency department: a case series. *Am J Emerg Med*. 2021;43:77-80. doi:10.1016/j.ajem.2021.01.050 **8.** Belley A, Lalonde Seguin D, Arhin F, Moeck G. Comparative in vitro activities of oritavancin, dalbavancin, and vancomycin against methicillin-resistant Staphylococcus aureus isolates in a nondividing state. *Antimicrob Agents Chemother*. 2016;60(7):4342-4345. doi:10.1128/AAC.00169-16 **9.** Dalvance. Package insert. Allergan Pharmaceuticals International Limited. **10.** Belley A, Neesham-Grenon E, McKay G, et al. Oritavancin kills stationary-phase and biofilm Staphylococcus aureus cells in vitro. *Antimicrob Agents Chemother*. 2009;53(3):918-925. doi:10.1128/AAC.00766-08 **11.** Brade KD, Rybak JM, Rybak MJ. Oritavancin: a new lipoglycopeptide antibiotic in the treatment of gram-positive infections. *Infect Dis Ther*. 2016;(5):1-15. doi:10.1007/s40121-016-0103-4 **12**. Whittaker C, Lodise TP, Nhan E, Reilly J. Expediting discharge in hospitalized, adult patients with skin and soft tissue infections who received empiric vancomycin therapy with oritavancin: description of findings from an institutional pathway. *Drugs Real World Outcomes*. 2020;7(suppl 1):30-35. doi:10.1007/s40801-020-00196-6 **13.** Estrada S, Lodise TP, Tillotson GS, Delaportas D. The real-world economic and clinical management of adult patients with skin and soft tissue infections (SSTIs) with oritavancin: data from two multicenter observational cohort studies. *Drugs Real World Outcomes*. 2020;7(suppl 1):6-12. doi:10.1007/s40801-020-00199-3 **14.** Data on file. Melinta Therapeutics. 2024. **15.** Kitabchi AE, Umpierrez GE, Miles JM, Fisher JN. Hyperglycemic crises in adult patients with diabetes. *Diabetes Care*. 2009;32(7):1335-1343. doi:10.2337/dc09-9032 **16.** Mitchell KH, Carlbom D, Caldwell E, Leary PJ, Himmelfarb J, Hough CL. Volume overload: prevalence, risk factors, and functional outcome in survivors of septic shock. *Ann Am Thorac Soc*. 2015;12(12):1837-1844. doi:10.1513/AnnalsATS.201504-187OC **17.** Lindley W, Kolaski S, Nhan E, Reilly J, Kardos A. Assessment of inpatient admissions and readmissions following one hour intravenous oritavancin administration in the emergency department. Poster presented at: ASHP Midyear Clinical Meeting & Exhibition; December 3-7, 2023; Anaheim, CA. **18.** Lindley W, Whittaker C, Szymborski S, Reilly J, Trivedi M. Acute bacterial skin and skin structure infections: a comparison of outpatient one-hour infusion oritavancin and inpatient vancomycin use. Poster presented at: IDWeek; October 16-17, 2024; Los Angeles, CA.

Important Safety Information (cont)

Warnings and Precautions (cont)

Osteomyelitis: Institute appropriate alternate antibacterial therapy in patients with confirmed or suspected osteomyelitis.

Prescribing oritavancin products in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of development of drug-resistant bacteria.

Adverse Reactions

The most common adverse reactions (≥3%) in patients treated with oritavancin products were headache, nausea, vomiting, limb and subcutaneous abscesses, and diarrhea. The adverse reactions occurring in ≥2 patients receiving KIMYRSA® were hypersensitivity, pruritus, chills and pyrexia.

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