Kimyrsa™ (oritavancin) for injection 1,200 mg

PROVEN ABSSSI* TREATMENT FOR YOUR AT-RISK PATIENTS

Identify common patient types who can benefit from KIMYRSA

Not actual patients.

*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).

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.

GIVE THEM BACK THEIR DAYS

IDENTIFY AT-RISK ABSSSI PATIENTS

Certain patients may be at increased risk of treatment failure with multidose antibiotics[1-3]

Single-dose antibiotic treatment can benefit many ABSSSI patients commonly seen in clinical practice, especially those with factors that increase the risk of treatment failure with multi-dose antibiotics.[1,4-6]

A lack of clear guidelines for assessing risk in ABSSSI patients can result in hospital admissions and treatment failure. This suggests that it may be beneficial to identify and appropriately treat high-risk ABSSSI patients with a fast-acting, single-dose therapy to improve outcomes and reduce unnecessary hospitalizations.[1-3,7]

Factors that can predispose ABSSSI patients to treatment failure and unnecessary hospitalization:

Diabetes

Impairment of peripheral blood flow to infection site increases the risk of treatment failure[1]

~1 in 3 adults with diabetes will develop chronic kidney disease, a complicating factor for ABSSSI treatment[3,8]

Renal impairment and obesity

Efficient **therapeutic exposure may be difficult** to achieve, increasing the likelihood of treatment failure[3]

Additional **monitoring may be required** with multidose IV antibiotics[3]

Vascular disease or congestive heart disease

Vascular compromise can lead to greater **difficulty in healing and tissue regeneration** following ABSSSI[9]

Advanced age

ABSSSI MRSA hospitalization is high in those 65+, likely due to increased comorbidities and/or diminished immune function[7]

Multi-dose IV therapy at an infusion center may be challenging for those who lack transportation options[2,6,10]

Outpatient treatment is preferred, as hospitalization increases the risk of falls, pressure ulcers, nosocomial infections, and delirium in elderly patients[11]

IV drug use

Ongoing IV drug use is both **a risk factor for ABSSSI and a concern for patient compliance** to an antibiotic regimen[7]

Use of PICC lines can lead to line infections, vascular access complications, and increased risk of rehospitalization for those discharged with OPAT[12-14]

Treat your ABSSSI patients with a single-dose antibiotic shown to help them avoid hospitalization and shorten LOS.

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.

IV=intravenous; LOS=length of stay; MRSA=methicillin-resistant *Staphylococcus aureus*; OPAT=outpatient parenteral antimicrobial therapy; PICC=peripherally inserted central catheter.

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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.

BREAK THE CYCLE OF ABSSSI ADMISSIONS WITH KIMYRSA

How oritavancin can benefit your at-risk patients

The efficacy and 1-dose administration of KIMYRSA® (oritavancin) can benefit a broad range of patient types, with specific product attributes being of particular benefit to patients at higher risk of treatment failure.[2,6,10-17]

Risk factor	Oritavancin benefit
• Diabetes[15] • Obesity[15] • Vascular disorders[15]	• 93% clinical success across all patients in a real-word study including a significant number of participants with comorbidities[15]* • Optional saline dilution and low 250-mL dosing[16]
• Mild to moderate renal impairment[16]	• A full course of therapy in one infusion with no monitoring or dosing adjustments[16]
• Advanced age[2,6,7,10]	• A single-dose course of therapy to ensure adherence with no dose adjustment for age[16] • Demonstrated efficacy in MRSA[17] • Outpatient treatment to avoid risks associated with hospitalization[10,11] • 93% clinical success across all patients in a real-world study in which nearly half of all 112 participants were ≥65[15†]
• IV drug use[7,12-14]	• Efficacy comparable to vancomycin in the Phase 3 SOLO trials, in which a third of patients were IV drug users[18‡] • A single-dose course of therapy to ensure adherence[16] • Freedom from PICC lines[6]

*Proportion of study population with comorbidities: diabetes, 37.5%; obesity, 30%; vascular disorders, 55.4%.[15]

†Proportion of study population ≥65 years of age: 39.3%.[15]

‡Early clinical response rates: 84.5% (n=218) vs 82.6% (n=214).[18]

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.

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

1-dose oritavancin helps keep appropriate patients out of the hospital

Avoid hospital admissions[10,15,19,20]

AVOIDED HOSPITALIZATION
when treated in an outpatient setting in 2 real-world studies.[15,19‡]

Prescribe in any convenient outpatient setting with no PICC line[10,15,20]

- **In the hospital**
  - ED
  - Hospital infusion center
  - Observation Unit
- **Outside the hospital**
  - Freestanding infusion center
  - Physician's office
  - Patients home

Shorten hospital stays[21]

≥2 DAY REDUCTION
in LOS with discharge to an outpatient infusion center or the patient's home§

Reduce readmissions[15,19,22,23]

Consistently low infection-related 30-day readmission rates of 0%-3.5%‖

Choose KIMYRSA to help patients achieve clinical cure and reduce unnecessary hospitalizations.

‡Results from 2 retrospective, real-world studies of a combined 227 patients treated in the ED, outpatient infusion center, or hospital-based infusion center.[15,19]

§Results from a real-world, retrospective, descriptive cohort study of 199 patients.[21]

‖Results from 4 distinct retrospective studies comprised of a combined 611 patients.[15,19,22,23]

ED=emergency department.

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CLINICAL EFFICACY AND SAFETY

Proven clinical efficacy vs vancomycin[17]

The efficacy of KIMYRSA® (oritavancin) has been established from adequate and well-controlled trials of another oritavancin product, ORBACTIV® (oritavancin), in patients with ABSSSI.

In the SOLO I and SOLO II clinical trials, oritavancin demonstrated efficacy comparable to vancomycin[17]*

Primary endpoint: Early clinical response rates at 48 to 72 hours†

ORBACTIV	82.2%	(435/529)
VANCOMYCIN	83.3%	(448/538)

Secondary endpoint: Reduction in lesion size at 48 to 72 hours‡

ORBACTIV	88.3%	(467/529)
VANCOMYCIN	86.1%	(463/538)

Secondary endpoint: Clinical success rates at days 14 to 24§

ORBACTIV	82.4%	(436/529)
VANCOMYCIN	83.5%	(449/538)

Study design: 2 global, multicenter, randomized, double-blind studies comparing the efficacy, safety, and noninferiority of single-dose intravenous ORBACTIV® vs intravenous vancomycin for 7 to 10 days in 1,959 adults with ABSSSIs (oritavancin, 978; vancomycin, 981)[17]

*Whereas the modified intent-to-treat (mITT) population included all randomized patients who received any study drug and was used to determine the primary efficacy endpoint in each study, the main patient population for these analyses was the mITT population, which consisted of the subset of patients within the mITT population with baseline gram-positive pathogen(s) known to cause ABSSSI.[17]

†Early clinical response defined as a composite of the cessation of spread or reduction in size of baseline lesion, absence of fever, and no rescue antibacterial drug at 48 to 72 hours.[17]

‡Patients achieving a ≥20% reduction in lesion area from baseline at 48 to 72 hours after initiation of therapy.[17]

§Investigator-assessed clinical success at days 14 to 24, defined as complete or nearly complete resolution of baseline signs and symptoms related to the primary ABSSSI site such that no further treatment with antibacterial drugs was needed.[17]

The safety of KIMYRSA® has been established from the adequate and well-controlled trials of another oritavancin product, ORBACTIV®, in patients with ABSSSI, and a PK study of KIMYRSA in patients with ABSSSI.[15,16,24]

PK=pharmacokinetics.

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.

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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 (cont)

Warnings and Precautions (cont)

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.

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.

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Cure ABSSSI with 1-dose KIMYRSA[15,16]

Patients with comorbidities may be at increased risk of treatment failure with multidose antibiotics[1-3]

1-dose oritavancin demonstrates clinical success, even for patients at high risk for treatment failure[15,16]

A full course of therapy in 1 hour without a PICC line ensures adherence, which can improve patient outcomes[6,16]

1 DOSE 1 HOUR VIAL

LEARN MORE AT KIMYRSA.COM

IMPORTANT SAFETY INFORMATION (cont)

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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melinta therapeutics

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