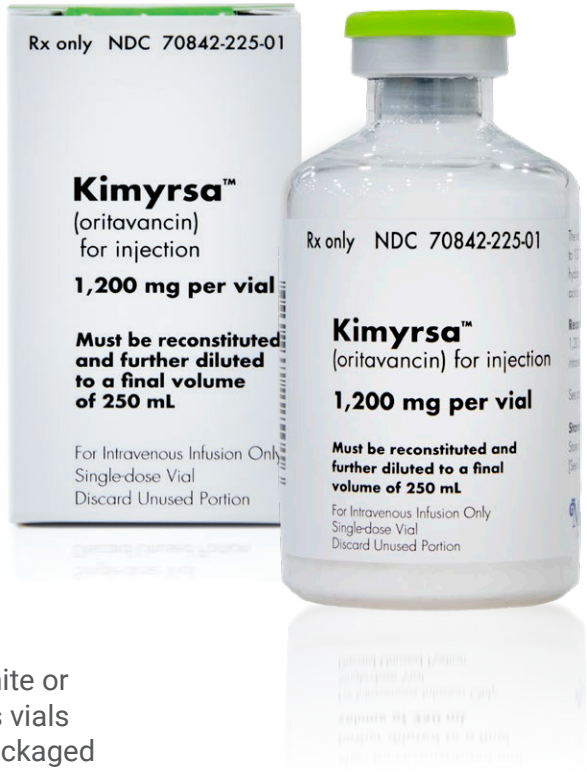
ORDER SHEET

Kimyrsa™ (oritavancin) for injection 1,200 mg



Order through your wholesaler or our Melinta Direct program today

NDC No.	70842-225-01
How supplied	KIMYRSA™ is supplied as a sterile white to off-white or pink lyophilized powder in single-dose clear glass vials containing 1,200 mg of oritavancin. One vial is packaged in a carton to supply a single 1,200 mg dose treatment.
Storage and handling	KIMYRSA™ vials should be stored at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F).
Carton size	1.7717 x 1.7717 x 3.0709 in (DxWxH)
Carton weight	0.10 lb/45.36 g
How to order	**KIMYRSA™ is available at your major wholesalers and through direct purchase.** Please use your normal ordering procedure to order KIMYRSA™ through the following wholesalers. • AmerisourceBergen Customer CARE • Anda Customer Service • Besse Medical Customer CARE • Cardinal Health Customer Service • McKesson Customer Support • Morris & Dickson Customer Service If KIMYRSA™ is not available at your wholesaler, please contact Melinta Direct for drop shipment. Melinta Direct Customer Service can be reached at 844-529-8993.

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MEDICAL INFORMATION

For medical inquiries or to report an adverse event, other safety-related information, or product complaints, please contact Medical Information.

1-844-MED-MLNT
(1-844-633-6568)

medinfo@melinta.com

melintamedicalinformation.com

INDICATION AND USAGE

KIMYRSA™ (oritavancin) for injection is 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 KIMYRSA™ and other antibacterial drugs, KIMYRSA™ 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

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

KIMYRSA™ is contraindicated in patients with known hypersensitivity to oritavancin products.

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 KIMYRSA™ dosing, consider a non-phospholipid dependent coagulation test such as a Factor Xa (chromogenic) assay or an alternative anticoagulant not requiring aPTT.

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

Infusion Related Reactions: Infusion reactions characterized by chest pain, back pain, chills and tremor have been observed with the use of oritavancin products (e.g. KIMYRSA™), 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 KIMYRSA™ and warfarin.

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

Prescribing KIMYRSA™ 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.

Please see accompanying Full Prescribing Information.

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