Single-dose ORBACTIV® (oritavancin) for the treatment of ABSSSI*

58-year-old diabetic with cellulitis

Lisa F, New York:
avid hiker with cellulitis

Background and presentation

- Lisa is a 58-year-old avid hiker and insulin-dependent type 1 diabetic
- During a hike, she developed a blister on her foot that burst and got infected
- Seven days later, she was seen by her primary care physician and was immediately referred to Dr. Davidson
- Lisa presented on an emergency basis from her primary care physician with a severe acute soft tissue infection without drainage

Evaluation

- BP: 126/81 mmHG
- Pulse: 101/min
- BMI: 32.4 kg/m^2
- Glucose: 450 mg/dL
- Temp: 101°F
- WBC: 14,300/mcL

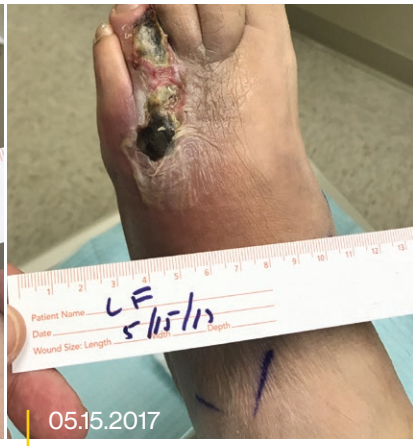
Treatment

Single 1200-mg dose of ORBACTIV® on 05.12.2017

Resolution of Lisa's cellulitis following single-dose ORBACTIV®

05.11.2017

Prior to single-dose ORBACTIV® 1200-mg infusion



05.15.2017

72 hours after ORBACTIV® infusion

05.25.2017

14 days after ORBACTIV® infusion

08.02.2017

Subsequent follow-up visit

"I chose ORBACTIV® as an initial treatment because it is a single-dose antibiotic and could potentially avoid a lengthy hospital stay for Lisa. In my experience with ORBACTIV®, Lisa was a good candidate for this drug and consequently responded to the treatment."

– Dr. David Davidson

The treating physician is a paid consultant of Melinta Therapeutics, LLC. This case study is an actual ABSSSI patient who was treated with a single 1200-mg dose of ORBACTIV®. No additional treatments were given to the patient for this infection. Individual results may vary.

For more ORBACTIV® patient stories, visit orbactiv.com/patient-stories

*INDICATION AND USAGE

ORBACTIV® (oritavancin) for injection is indicated for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSIs) caused or suspected to be caused by susceptible isolates of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-susceptible [MSSA] and -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 ORBACTIV® and other antibacterial drugs, ORBACTIV® 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 ORBACTIV® administration because the activated partial thromboplastin time (aPTT) test results are expected to remain falsely elevated for approximately 120 hours (5 days) after ORBACTIV® administration.

ORBACTIV® is contraindicated in patients with known hypersensitivity to ORBACTIV®.

Please see reverse for additional Important Safety Information.

Orbactiv™ (oritavancin) for injection 1200 mg

Efficacy and Efficiency in One Dose

Clinical response rates with the largest MRSA subset in a single-dose ABSSSI program[1-3]

Pooled response rates for SOLO I and SOLO II clinical trials*

Endpoints	ORB‖ (n=978)	VAN‖ (n=981)	MRSA: ORB¶ (n=204)	MRSA: VAN¶ (n=201)
Early clinical response (primary endpoint)†	81.2% (794)	80.9% (794)	81.4% (166)	80.6% (162)
≥20% reduction in lesion size (secondary endpoint)‡	86.4% (845)	84.1% (825)	93.1% (190)	87.1% (175)
Clinical success (secondary endpoint)§	81.2% (794)	80.2% (787)	83.3% (170)	84.1% (169)

*Pooled data calculated based on SOLO I and SOLO II data in Prescribing Information. SOLO I and SOLO II were two identical, randomized, double-blind, non-inferiority, Phase 3 trials comparing ORBACTIV® 1200 mg to vancomycin 1 g or 15 mg/kg BID for 7-10 days.
†Early clinical response: composite of the cessation of spread or reduction in size of baseline lesion, absence of fever, and no rescue antibacterial drug at 48-72 hours.
‡Patients achieving a 20% or greater reduction in lesion area from baseline at 48-72 hours after initiation of therapy.
§Clinical success: complete or nearly complete resolution of baseline signs and symptoms at post-therapy evaluation at days 14-24.
‖Modified intent-to-treat population.
¶Microbiological intent-to-treat population of the SOLO pool.

ORBACTIV® is covered and reimbursed by most health plans[4]*

For information about coding and financial assistance for patients, please contact:

1-844-ORBACTIV (1-844-672-2284)
Monday - Friday, 8:00 AM - 8:00 PM ET

orbactivassistanceprogram@melinta.com

*Melinta Therapeutics, LLC, does not guarantee that coverage or payment will occur for any particular claim. Please consult payers for all coverage, coding and reimbursement.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions

Coagulation test interference: ORBACTIV® 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. ORBACTIV® has also been shown to elevate D-dimer concentrations up to 72 hours.

Hypersensitivity reactions, including anaphylaxis, have been reported with the use of antibacterial agents including ORBACTIV®. Discontinue infusion if signs of acute hypersensitivity occur. Monitor closely patients with known hypersensitivity to glycopeptides.

Infusion Related Reactions: Administer ORBACTIV® over 3 hours to minimize infusion-related reactions. Infusion reactions characterized by chest pain, back pain, chills and tremor have been observed with the use of ORBACTIV®, including after the administration of more than one dose of ORBACTIV® during a single course of therapy. Stopping or slowing the infusion may result in cessation of these reactions.

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

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

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

Prescribing ORBACTIV® in the absence of a proven or strongly suspected bacterial infection 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 ORBACTIV® were headache, nausea, vomiting, limb and subcutaneous abscesses, and diarrhea.

Please see reverse for complete Indication and additional Important Safety Information. Please see accompanying Full Prescribing Information.

References: 1. ORBACTIV® [package insert]: Melinta Therapeutics, LLC; 2019. **2.** Corey GR, Kabler H, Mehra P, et al; SOLO I Investigators. Single-dose oritavancin in the treatment of acute bacterial skin infections *N Engl J Med*. 2014;370(23):2180-2190. **3.** Corey GR, Good S, Jiang H, et al; SOLO II Investigators. Single-dose oritavancin versus 7-10 days of vancomycin in the treatment of gram-positive acute bacterial skin and skin structure infections: the SOLO II noninferiority study. *Clin Infect Dis*. 2015;60(2):254-262. **4.** Data on file, Melinta Therapeutics, LLC.

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Efficacy and Efficiency in One Dose