ORDER SHEET



Order through your wholesaler or our Melinta Direct program today



Three 400-mg vials are packaged in a carton to supply a single 1200-mg dose treatment.

NDC No.

70842-140-03

How supplied

ORBACTIV® is supplied as sterile, white to off-white lyophilized powder equivalent to 400 mg of oritavancin in a single use 50-mL clear glass vial. Three vials are packaged in a carton to supply a single 1200-mg dose treatment.

Storage and handling

ORBACTIV® 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

5.125 x 2.125 x 3 in (LxWxH)

Carton weight

0.22 lb/100 g

How to order

ORBACTIV® is available at your major wholesalers and through direct purchase.

Please use standard ordering procedure through your wholesaler by calling your wholesaler's customer service number listed below:

- AmerisourceBergen Customer CARE: (844) 222-2273
- Anda Customer Service: (800) 331-2632
- Besse Medical Customer CARE: (800) 543-2111
- Cardinal Health Customer Service: (800) 926-3161
- H. D. Smith Customer Service: (800) 628-2977
- McKesson Customer Support: (855) 625-4677
- Morris & Dickson Customer Service: (800) 388-3833

If ORBACTIV® is not available at your wholesaler, please contact Melinta Direct for drop ship. Please feel free to contact Melinta Direct Customer Service Information with any questions at 844-529-8993.



Medical Information

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







INDICATION AND USAGE

ORBACTIV® (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 -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 may remain falsely elevated for approximately 120 hours (5 days) after ORBACTIV® administration.

ORBACTIV® 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 oritavancin 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 ORBACTIV®. Discontinue infusion if signs of acute hypersensitivity occur. Closely monitor 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 oritavancin products (e.g. ORBACTIV®), 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 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 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 ORBACTIV® were headache, nausea, vomiting, limb and subcutaneous abscesses, and diarrhea.

Please see accompanying Full Prescribing Information.



