Preparation of ORBACTIV® (oritavancin)

Preparation instructions

Orbactiv™ (oritavancin) for injection 1200 mg

Aseptic technique should be used

1 Add Sterile Water

Add 40 mL of Sterile Water for Injection to each of three ORBACTIV® 400 mg vials to reconstitute.

DO NOT USE NORMAL SALINE. MAY CAUSE PRECIPITATION.

2 Swirl Gently

Swirl gently to avoid foaming and ensure all ORBACTIV® powder is completely reconstituted. May not dissolve immediately.

3 Inspect

Inspect each vial visually for particulate matter. Solution should appear to be clear, colorless to pale yellow..

4 Withdraw and Discard

Withdraw and discard 120 mL from the one liter D5W IV bag.

5 Transfer

Transfer 40 mL from each of the three reconstituted vials to the one liter D5W IV bag to dilute to bring to a final concentration of 1.2 mg/mL.

Stability of Diluted IV Solution

(includes three hours for administration)
Six hours at room temperature (20° to 25°C or 68° to 77°F)
Twelve hours refrigerated (2°C to 8°C or 36°F to 46°F).

Supplies

Three ORBACTIV® 400 mg vials
One Liter D5W IV Bag
120 mL Sterile Water for Injection.

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.

Dosage and Administration

ORBACTIV® is administered as a single 1200 mg dose by IV infusion over three hours in patients 18 years and older. Single dose ORBACTIV® does not require dose adjustment for mild-to-moderate renal* or mild-to-moderate hepatic† impairment, weight, age (≥18 years of age), race, or gender.

*Mild renal impairment CrCL 50-79 mL/min, moderate renal impairment CrCL 30-49 mL/min

†Moderate hepatic impairment (Child-Pugh Class B)

Incompatibilities

IV substances, additives or other medications mixed in normal saline should not be added to single use vials or infused simultaneously with ORBACTIV® through the same IV line or through a common intravenous port. Drugs formulated at a basic or neutral pH may be incompatible with ORBACTIV®. If the same IV line is used for sequential infusion of additional medications, the line should be flushed before and after infusion of ORBACTIV® with D5W.

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.

Please see reverse for complete Indication and Important Safety Information.

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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

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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.

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