ZERBAXA®
ceftolozane and tazobactam
for injection

Indicated for the Treatment of HABP/VABP

ZERBAXA is indicated for the treatment of adult patients (18 years and older) with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP), caused by the following susceptible Gram-negative microorganisms: *Enterobacter cloacae, Escherichia coli, Haemophilus influenzae, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa,* and *Serratia marcescens.*

To reduce the development of drug-resistant bacteria and maintain the effectiveness of ZERBAXA and other antibacterial drugs, ZERBAXA should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Important Safety Information

- **Patients with renal impairment:** Dose adjustment is required for adult patients with CrCl 50 mL/min or less. All doses of ZERBAXA are administered over 1 hour. Monitor CrCl at least daily in patients with changing renal function and adjust the dose of ZERBAXA accordingly.
- **Hypersensitivity:** ZERBAXA is contraindicated in patients with known serious hypersensitivity to the components of ZERBAXA (ceftolozane/tazobactam), piperacillin/tazobactam, or other members of the beta-lactam class. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients receiving beta-lactam antibacterials. Before initiating therapy with ZERBAXA, make careful inquiry about previous hypersensitivity reactions to cephalosporins, penicillins, or other beta-lactams. If an anaphylactic reaction to ZERBAXA occurs, discontinue use and institute appropriate therapy
- ***Clostridioides difficile*–associated diarrhea (CDAD),** ranging from mild diarrhea to fatal colitis, has been reported with nearly all systemic antibacterial agents, including ZERBAXA. Careful medical history is necessary because CDAD has been reported to occur more than 2 months after the administration of antibacterial agents. If CDAD is confirmed, antibacterial use not directed against *C. difficile* should be discontinued, if possible.

Important Safety Information is continued on the next page.

Important Dosing Information for ZERBAXA in Adult Patients With HABP/VABP

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Vials not actual size

1.5 g 1.5 g 1-HOUR INFUSION

The recommended dose of ZERBAXA in adult patients with HABP/VABP and creatinine clearance (CrCl) greater than 50 mL/min is 3 grams (two 1.5 g vials) over 1-hour period every 8 hours for 8 to 14 days.

- The dose selected was based on a phase 1 study where 3-gram dose achieved target concentration in the epithelial lining fluid for 100% of the dosing interval.

Renal dosing adjustments for patients with HABP/VABP per estimated CrCl (mL/min)[a,b]

- 30 to 50 1.5 g (1 g and 0.5 g) intravenously every 8 hours
- 15 to 29 750 mg (500 mg and 250 mg) intravenously every 8 hours
- For patients with end-stage renal disease on hemodialysis: a single loading dose of 2.25 g (1.5 g and 0.75 g) followed by a 450-mg (300 mg and 150 mg) maintenance dose administered every 8 hours for the remainder of the treatment period (on hemodialysis days, administer the dose at the earliest possible time following completion of dialysis).

[a]Creatine clearance (CrCl) estimated using Cockcroft-Gault formula.
[b]All doses of ZERBAXA are administered over 1 hour.

Important Safety Information (*continued*)

- **Development of drug-resistant bacteria:** Prescribing ZERBAXA in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and risks the development of drug-resistant bacteria.

- **Adverse reactions in adult patients with HABP/VABP:** The most common adverse reactions occurring in ≥5% of adult patients receiving ZERBAXA in the HABP/VABP trial were hepatic transaminase increased (11.9%), renal impairment/renal failure (8.9%), and diarrhea (6.4%).

Before prescribing ZERBAXA® (ceftolozane and tazobactam) for injection (1.5 g), please read the accompanying Prescribing Information.

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