

Zerbaxa® (ceftolozane/tazobactam) – New indication

- On June 3, 2019, the [FDA announced](#) the approval of [Merck's Zerbaxa \(ceftolozane/tazobactam\)](#), for the treatment of patients 18 years and older with hospital-acquired bacterial pneumonia (HABP) and ventilator-associated bacterial pneumonia (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*.
- Zerbaxa is also approved for complicated intra-abdominal infections, used in combination with [metronidazole](#); and complicated urinary tract infections, including pyelonephritis.
- HABP and VABP occur in patients in hospitals or other health care facilities and can be caused by a variety of bacteria. According to data from the Centers for Disease Control and Prevention, HABP and VABP are currently the second most common type of hospital-acquired infection in the U.S., and are a significant issue in patients in the intensive care unit.
- The approval of Zerbaxa's new indication was based on a double-blind study in 726 adult patients hospitalized with HABP/VABP. The study compared Zerbaxa to [meropenem](#) for 8 to 14 days of therapy. Efficacy was assessed based on all-cause mortality at day 28 and clinical cure, defined as complete resolution or significant improvement in signs and symptoms of the index infection at the test-of-cure visit which occurred 7 to 14 days after the end of treatment.
 - All-cause mortality at day 28 was 24.0% and 25.3% for Zerbaxa and meropenem, respectively (treatment difference 1.1; 95% CI: -5.13, 7.39).
 - Clinical cure rates were 54.4% and 53.3% for Zerbaxa and meropenem, respectively (treatment difference 1.1; 95% CI: -6.17, 8.29).
- For treatment of HABP/VABP, the most common adverse reactions (≥ 5%) with Zerbaxa use were increase in hepatic transaminases, renal impairment/renal failure, and diarrhea.
- The recommended dosage of Zerbaxa for adult patients with HABP/VABP is 3 grams (ceftolozane 2 grams/tazobactam 1 gram) administered every 8 hours by intravenous infusion over 1 hour for 8 to 14 days.
 - The duration of therapy should be guided by the severity and site of infection and the patient's clinical and bacteriological progress.
 - Refer to the Zerbaxa drug label for dosing for its other indications.