Brand Name: Zerbaxa
Generic: ceftolozane, tazobactam
Type: small molecule
Year Accepted/Phase: 2014

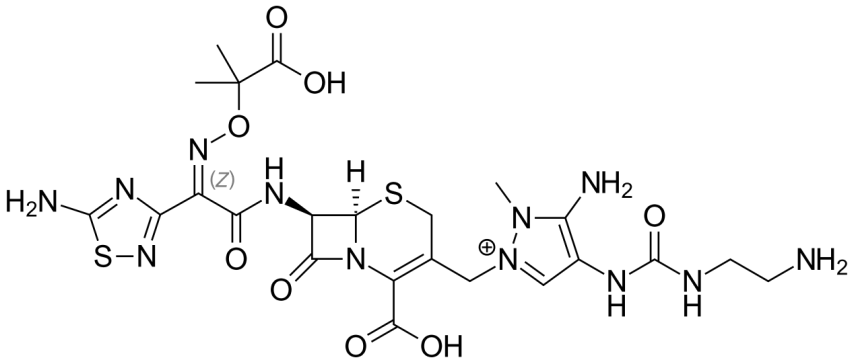
Mechanism:

Ceftolozane: Inhibits bacterial cell wall synthesis by binding to penicillin-binding proteins, leading to cell lysis and death.

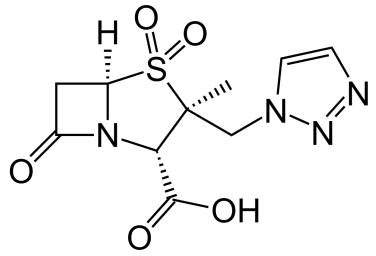
Tazobactam: Inhibits beta-lactamase enzymes produced by bacteria, preventing the degradation of ceftolozane and extending its spectrum of activity.

Chemical Structure:

ceftolozane



tazobactam



Indication:

Zerbaxa is indicated for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, and complicated intra-abdominal infections (cIAI), in combination with metronidazole.

Clinical trials:

ASPECT-cIAI Trial (Phase III)

Pubmed: https://pubmed.ncbi.nlm.nih.gov/25670823/

Purpose: Evaluate the efficacy and safety of Zerbaxa in combination with metronidazole for the treatment of complicated intra-abdominal infections (cIAI).
Dates: Conducted from 2011 to 2014.
Results: The ASPECT-cIAI trial demonstrated that Zerbaxa, in combination with metronidazole, was non-inferior to meropenem in achieving clinical cure rates. The clinical cure rate at the test-of-cure visit was 83% for the Zerbaxa plus metronidazole group versus 87% for the meropenem group.
Impact: The trial supported the approval of Zerbaxa for the treatment of cIAI, providing an effective alternative to existing therapies.

ASPECT-cUTI Trial (Phase III)

Pubmed: https://pubmed.ncbi.nlm.nih.gov/25931244/

Purpose: Assess the efficacy and safety of Zerbaxa for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis.
Dates: Conducted from 2011 to 2014.
Results: The ASPECT-cUTI trial showed that Zerbaxa was non-inferior to levofloxacin in terms of the composite endpoint of microbiological eradication and clinical cure at the test-of-cure visit. The overall response rate was 79% for Zerbaxa versus 58% for levofloxacin.
Impact: These results led to the approval of Zerbaxa for cUTI, offering a new treatment option, particularly for infections caused by drug-resistant pathogens.

CREDIBLE-CR Trial (Phase III)

Pubmed: https://pubmed.ncbi.nlm.nih.gov/33058795/

Purpose: Evaluate the efficacy and safety of Zerbaxa for the treatment of infections caused by carbapenem-resistant Enterobacteriaceae (CRE).
Dates: Conducted from 2016 to 2018.
Results: The CREDIBLE-CR trial demonstrated that Zerbaxa was effective in treating infections caused by CRE, with a clinical cure rate of 81%. The safety profile was consistent with previous studies.
Impact: The trial provided evidence for the use of Zerbaxa in treating multidrug-resistant infections, highlighting its role in addressing the growing challenge of antibiotic resistance.