ZERBAXA®
ceftolozane and tazobactam
for injection (1.5 g)

Broad Availability of Antimicrobial Susceptibility Testing Devices

Indications

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.*

ZERBAXA is indicated for the treatment of adult and pediatric patients (birth to less than 18 years old) with complicated urinary tract infections (cUTI), including pyelonephritis, caused by the following susceptible Gram-negative microorganisms: *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis,* and *Pseudomonas aeruginosa.*

ZERBAXA used in combination with metronidazole is indicated for the treatment of adult and pediatric patients (birth to less than 18 years old) with complicated intra-abdominal infections (cIAI) caused by the following susceptible Gram-negative and Gram-positive microorganisms: *Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, Bacteroides fragilis, Streptococcus anginosus, Streptococcus constellatus,* and *Streptococcus salivarius.*

Usage

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 for ZERBAXA

- **Patients with renal impairment:** Decreased efficacy of ZERBAXA has been observed in patients with baseline CrCl of 30 to ≤50 mL/min. In a clinical trial of adult patients, patients with cIAIs with CrCl >50 mL/min had a clinical cure rate of 85.2% when treated with ZERBAXA plus metronidazole vs 87.9% when treated with meropenem. In the same trial, patients with CrCl 30 to ≤50 mL/min had a clinical cure rate of 47.8% when treated with ZERBAXA plus metronidazole vs 69.2% when treated with meropenem. A similar trend was also seen in the cUTI trial. 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.

Before prescribing ZERBAXA, please read the accompanying Prescribing Information.

Available Antimicrobial Susceptibility Testing Devices for Ceftolozane and Tazobactam

Thermo Scientific™ Sensititre™ Gram-Negative Standard MIC Plates

Ordering Information:

Description	Format	Pack Size	Ref.
Sensititre Gram-Negative Novel Drug Plate	• Multi-antibiotic (9) plates including Ceftolozane/Tazobactam • MIC range: 0.06/4 – 8/4µg/mL	10x Microtitre Plates	MDRGN3F
Sensititre Gram-Negative Novel Drug Plate with Colistin	• Multi-antibiotic (10) plates including Ceftolozane/Tazobactam • MIC range: 0.06/4 – 8/4µg/mL	10x Microtitre Plates	MDRGNXXF
Sensititre Gram-Negative Plate	• Multi-antibiotic (12) plates including Ceftolozane/Tazobactam • MIC range: 2/4 – 16/4µg/mL	10x Microtitre Plates	GN7F
Sensititre Gram-Negative with Colistin	• Multi-antibiotic (5) and multi-isolate plates including Ceftolozane/Tazobactam • MIC range: 0.25/4 – 8/4µg/mL	10x Microtitre Plates	GNX4F

For more information, contact your local Thermo Fisher Scientific Microbiology representative at microbiology@thermofisher.com or visit www.thermofisher.com/AST.
Thermo Scientific and Sensititre are trademarks of Thermo Fisher Scientific Inc. and its subsidiaries.

Photo credit: Thermo Fisher Scientific

- Manual to fully automated plate reading.
- MIC results.
- For in vitro diagnostic use only. Observe approved biohazard precautions and aseptic techniques. This product is to be used only by adequately trained and qualified laboratory personnel. Sterilize all biohazard waste before disposal.

Susceptibility Disk From Hardy Diagnostics

Ordering Information:

Description	Catalog Number
Ceftolozane/Tazobactam 1x50 cartridge (30 mg/10 µg)	Z9341
Ceftolozane/Tazobactam 5x50 cartridge (30 mg/10 µg)	Z9345

Photo credit: Hardy Diagnostics

- Available in single cartridge (Z9341) or packs of 5 (Z9345).
- Compatible with BBL dispenser.
- For in vitro diagnostic use only. Observe approved biohazard precautions and aseptic techniques. This product is to be used only by adequately trained and qualified laboratory personnel. Sterilize all biohazard waste before disposal.

Visit www.hardydiagnostics.com for complete Instructions for Use (IFU). (800) 266-2222 HardyDisk is a registered trademark of Hardy Diagnostics.

Important Safety Information for ZERBAXA® (ceftolozane and tazobactam) *(continued)*

- ***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.
- **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.

Available Antimicrobial Susceptibility Testing Devices for Ceftolozane and Tazobactam

MIC Test Strip From Liofilchem®

Ordering Information:

Description	µg/mL	Strips/Box	Ref.
Ceftolozane-Tazobactam	0.016/4 – 256/4	10	921461
Ceftolozane-Tazobactam	0.016/4 – 256/4	30	92146
Ceftolozane-Tazobactam	0.016/4 – 256/4	100	921460

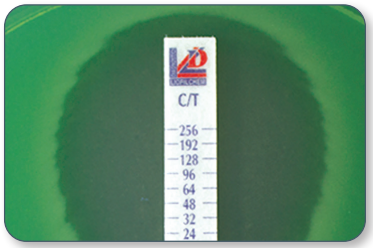

Photo credit: Liofilchem

- For in vitro diagnostic use only. Observe approved biohazard precautions and aseptic techniques. This product is to be used only by adequately trained and qualified laboratory personnel. Sterilize all biohazard waste before disposal.

For further information or purchase orders, contact Liofilchem at orders@liofilchem.us, call (781) 902-0312, or visit www.liofilchem.com.
Liofilchem and the Liofilchem company logo are registered trademarks of LIOFILCHEM s.r.l.

Additionally, Liofilchem MIC Test Strip can also be purchased at Fisher Healthcare. Visit fisherhealthcare.com, call (800) 640-0640, or contact your Fisher Healthcare sales representative to learn more.

VITEK® 2 AST-N801 and AST-XN09, Gram-Negative Susceptibility Cards From bioMérieux

Ordering Information:

Description	MIC Calling Range for Ceftolozane/Tazobactam in µg/mL	Cards/Box	Ref.
AST-N801	• Ceftolozane MIC range: 0.25-32 µg/mL • Tazobactam: 4 µg/mL	20 cards per box	423416
AST-XN09	• Ceftolozane MIC range: 0.25-32 µg/mL • Tazobactam: 4 µg/mL	20 cards per box	423425
AST-XN15	• Ceftolozane MIC range: 0.25-32 µg/mL • Tazobactam: 4 µg/mL	20 cards per box	423829


Photo credit: bioMérieux SA
VITEK 2 Cards

- The VITEK® 2 AST-N801 (Non-fermenter), AST-XN09 (Extension Card), and AST-XN15 (Extension Card), Gram-Negative Susceptibility Cards From bioMerieux are intended for use with the VITEK 2 system in clinical laboratories as an in vitro test to determine the susceptibility of select aerobic Gram-negative bacilli to antimicrobial agents when used as instructed in VITEK 2 labeling.
- For in vitro diagnostic use only. Observe approved biohazard precautions and aseptic techniques. This product is to be used only by adequately trained and qualified laboratory personnel. Sterilize all biohazard waste before disposal.
- Laboratories must have the latest version of VITEK 2 software to utilize the AST-XN09 Gram-negative extension card.
  — Contact bioMérieux at (800) 682-2666 for information about software for VITEK 2.

For more information, visit www.biomerieux-usa.com/clinical/vitek-2-healthcare. For more information on VITEK 2 Cards call (800) 682-2666. To order online, please visit: www.biomerieuxDIRECT.com.
VITEK is a registered trademark belonging to bioMérieux SA or one of its subsidiaries.

Important Safety Information for ZERBAXA® (ceftolozane and tazobactam) *(continued)*

- **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%).
- **Adverse reactions in adult patients with cIAI or cUTI:** The most common adverse reactions occurring in ≥7% of pediatric patients receiving ZERBAXA in the cIAI trial were diarrhea (17%), thrombocytosis (16%), pyrexia (13%), abdominal pain (11%), vomiting (10%), increased aspartate aminotransferase (7%), and anemia (7%). The most common adverse reactions occurring in ≥7% of pediatric patients receiving ZERBAXA in the cUTI trial were thrombocytosis (9%), leukopenia (8%), diarrhea (7%), and pyrexia (7%).

Available Antimicrobial Susceptibility Testing Devices for Ceftolozane and Tazobactam

ETEST® C/T 256 Strip From bioMérieux

Ordering Information:

Description	µg/mL	Strips/Box	Ref.
ETEST Ceftolozane/Tazobactam	Each strip contains: • Ceftolozane MIC range: 0.016–256 µg/mL • Tazobactam: 4 µg/mL	Single pack: 30 test strips	414 445

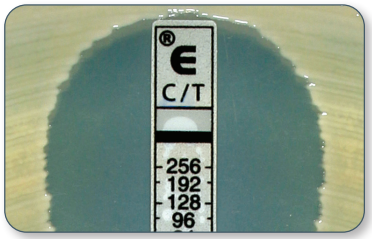

Photo credit: bioMérieux

- The ETEST C/T 256 strip is an in vitro quantitative technique of Antimicrobial Susceptibility Testing (AST) for determining a Minimum Inhibitory Concentration (MIC) for ceftolozane/tazobactam.
- For in vitro diagnostic use only. Observe approved biohazard precautions and aseptic techniques. This product is to be used only by adequately trained and qualified laboratory personnel. Sterilize all biohazard waste before disposal.

For more information, visit www.biomerieux-usa.com/etest. Customer Service (800) 682-2666. To order please visit: www.biomerieuxDIRECT.com.
ETEST is a registered trademark of bioMérieux.

MicroScan® Gram-Negative Susceptibility Panels From Beckman Coulter, Inc.

Ordering Information:

Description	Available Dilutions for Ceftolozane/Tazobactam in µg/mL	Panels/Box	Ref.
Neg MIC 56	• Ceftolozane /Tazobactam 2/4 – 8/4	20 panels	C42464
Neg MIC 53	• Ceftolozane /Tazobactam 2/4 – 8/4	20 panels	B1017-432
Neg/Urine Combo 87	• Ceftolozane /Tazobactam 2/4 – 8/4	20 panels	B1017-437
Detect Neg MIC 2	• Ceftolozane /Tazobactam 2/4 – 8/4	20 panels	B1010-102B

Photo credit: Beckman Coulter MicroScan Panels

- The MicroScan Gram-Negative Susceptibility panels are intended for use with the MicroScan Systems or as a manual read panel in clinical laboratories as in vitro diagnostic tests to determine the susceptibility of select aerobic Gram-negative bacilli to antimicrobial agents when used as instructed in the MicroScan package labeling.
- For in vitro diagnostic use only. Observe approved biohazard precautions and aseptic techniques. This product is to be used only by adequately trained and qualified laboratory personnel. Sterilize all biohazard waste before disposal.

Contact your Beckman Coulter Representative or dial (800) 677-7226 for technical microbiology information. Call (800) 526-3821 for Beckman Coulter Customer Service. Visit https://www.beckmancoulter.com for more information. MicroScan is a registered trademark of Beckman Coulter, Inc.

Important Safety Information for ZERBAXA® (ceftolozane and tazobactam) *(continued)*

- **Adverse reactions in pediatric patients with cIAI or cUTI:** The most common adverse reactions occurring in ≥7% of pediatric patients receiving ZERBAXA in the cIAI trial were diarrhea (17%), thrombocytosis (16%), pyrexia (13%), abdominal pain (11%), vomiting (10%), increased aspartate aminotransferase (7%), and anemia (7%). The most common adverse reactions occurring in ≥7% of pediatric patients receiving ZERBAXA in the cUTI trial were thrombocytosis (9%), leukopenia (8%), diarrhea (7%), and pyrexia (7%).

Available Antimicrobial Susceptibility Testing Devices for Ceftolozane and Tazobactam

BD Phoenix™ Emerge™ Gram-Negative Susceptibility Panels From Becton Dickinson

Ordering Information:

Description	Available Dilutions for Ceftolozane/Tazobactam in µg/mL	Panels/SP	Ref.
BD Phoenix Emerge NMIC-305	• Ceftolozane/Tazobactam 0.05/4 – 8/4	25	449294
BD Phoenix Emerge NMIC-306	• Ceftolozane/Tazobactam 1/4 – 8/4	25	449292
BD Phoenix Emerge NMIC-311	• Ceftolozane/Tazobactam 1/4 – 8/4	25	449452
BD Phoenix Combo NMIC/ID-308	• Ceftolozane/Tazobactam 1/4 – 8/4	25	449282
BD Phoenix AST-only NMIC-308	• Ceftolozane/Tazobactam 1/4 – 8/4	25	449065

Photo credit: Becton Dickinson

- The BD Phoenix Emerge combination and AST-only panels are intended for use on the BD Phoenix identification and susceptibility testing instruments in clinical laboratories as an in vitro diagnostic test to determine the susceptibility to select aerobic Gram-negative bacilli to antimicrobial agents as instructed by the BD Phoenix labeling.
- For in vitro diagnostic use only. Observe approved biohazard precautions and aseptic techniques. This product is to be used only by adequately trained and qualified laboratory personnel. Sterilize all biohazard waste before disposal.
- Laboratories will need to ensure the BD Phoenix instrument is configured to match the panel type. For additional questions, contact BD at (800) 638-8663.

For more information, contact your local BD Diagnostic Account Representative or visit www.bd.com/en-us/offerings/capabilities/microbiology-solutions/identification-and-susceptibility-testing.
BD Phoenix is a trademark of Becton, Dickinson and Company.

FDA and CLSI Approved Susceptibility Interpretive Criteria for Ceftolozane/Tazobactam[1]

Description	Minimum Inhibitory Concentrations (mcg/mL)			Disk Diffusion Zone Diameter (mm)		
	S	I	R	S	I	R
Enterobacteriaceae	≤2/4	4/4	≥8/4	≥21	18–20	≤17
Pseudomonas aeruginosa	≤4/4	8/4	≥16/4	≥21	17–20	≤16

S = susceptible, I = intermediate, R = resistant.

To order clinical isolates to perform verification testing for ceftolozane and tazobactam, contact the CDC or send requests via the following URL: https://www.cdc.gov/drugresistance/resistance-bank/currently-available.html

Important Safety Information for ZERBAXA® (ceftolozane and tazobactam) (*continued*)

- **Pediatric Use:** There is insufficient information to recommend dosage adjustment for pediatric patients younger than 18 years of age with cIAI and cUTI with eGFR 50 mL/min/1.73m^2 or less. ZERBAXA is not recommended in pediatric patients who have an eGFR 50 mL/min/1.73m^2 or less. Pediatric patients born at term or pre-term may not have an eGFR of 50 mL/min/1.73m^2 or greater at birth or within the first few months of life.

Before prescribing ZERBAXA, please read the accompanying Prescribing Information.

Reference: 1. U.S. Food and Drug Administration. FDA-Recognized Antimicrobial Susceptibility Test Interpretive Criteria. Accessed July 18, 2022. https//www.fda.gov/STIC.