

ANTIMICROBIAL SUSCEPTIBILITY TESTING DEVICES & DIAGNOSTICS

INDICATIONS AND USAGE

Complicated Intra-Abdominal Infections (cIAI)

AVYCAZ (ceftazidime and avibactam), in combination with metronidazole, is indicated for the treatment of complicated intra-abdominal infections (cIAI) in adult and pediatric patients 3 months or older caused by the following susceptible Gram-negative microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Enterobacter cloacae*, *Klebsiella oxytoca*, *Citrobacter freundii* complex, and *Pseudomonas aeruginosa*.

Complicated Urinary Tract Infections (cUTI), including Pyelonephritis

AVYCAZ is indicated for the treatment of complicated urinary tract infections (cUTI) including pyelonephritis in adult and pediatric patients 3 months or older caused by the following susceptible Gram-negative microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Citrobacter freundii* complex, *Proteus mirabilis*, and *Pseudomonas aeruginosa*.

Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP)

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

Usage

To reduce the development of drug-resistant bacteria and maintain the effectiveness of AVYCAZ and other antibacterial drugs, AVYCAZ should be used to treat only indicated infections that are proven or strongly suspected to be caused by susceptible bacteria.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

AVYCAZ is contraindicated in patients with known serious hypersensitivity to the components of AVYCAZ (ceftazidime and avibactam), avibactam-containing products, or other members of the cephalosporin class.

**Please see additional Important Safety Information throughout.
Please also see full enclosed Prescribing Information.**



Avycaz
ceftazidime and avibactam
for injection (2.5 g)

Ceftazidime/Avibactam Susceptibility Testing Devices

Thermo Scientific™ Sensititre™ Gram-negative Standard MIC Plates

Description	Format	Pack Size	Reference
Sensititre Gram-negative Plate	• Multi-antibiotic (12) plates including Ceftazidime/Avibactam	10x Microtitre Plates	GN6F
Sensititre Gram-negative with Colistin	• Multi-antibiotic (5) and multi-isolate plates including Ceftazidime/Avibactam	10x Microtitre Plates	GNX4F
Sensititre Gram-negative Novel Drug Plate	• Multi-antibiotic (9) plates including Ceftazidime/Avibactam	10x Microtitre Plates	MDRGN1F
Sensititre Gram-negative Novel Drug Plate with Colistin	• Multi-antibiotic (10) plates including Ceftazidime/Avibactam	10x Microtitre Plates	MDRGNX1F

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.

Susceptibility Disks: Hardy Diagnostics

Description	Catalog Number
HardyDisk AST Ceftazidime/Avibactam (CZA50), 1x50 disks (30µg/20µg)	Z9351
HardyDisk AST Ceftazidime/Avibactam (CZA50), 5x50 disks (30µg/20µg)	Z9355

HardyDisk is a registered trademark of Hardy Diagnostics.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

- In a Phase 3 cIAl trial in adult patients, clinical cure rates were lower in a subgroup of patients with baseline creatinine clearance (CrCl) of 30 to less than or equal to 50 mL/min compared to those with CrCl greater than 50 mL/min. The reduction in clinical cure rates was more marked in patients treated with AVYCAZ plus metronidazole compared to meropenem-treated patients. Within this subgroup, patients treated with AVYCAZ received a 33% lower daily dose than is currently recommended for patients with CrCl of 30 to less than or equal to 50 mL/min. Clinical cure rate in patients with normal renal function/mild renal impairment (CrCl greater than 50 mL/min) was 85% (322/379) with AVYCAZ plus metronidazole vs 86% (321/373) with meropenem, and clinical cure rate in patients with moderate renal impairment (CrCl 30 to less than or equal to 50 mL/min) was 45% (14/31) with AVYCAZ plus metronidazole vs 74% (26/35) with meropenem. The decreased clinical response was not observed for patients with moderate renal impairment at baseline (CrCl 30 to less than or equal to 50 mL/min) in the Phase 3 cUTI trials or the Phase 3 HABP/VABP trial. Monitor CrCl at least daily in adult and pediatric patients with changing renal function and adjust the dosage of AVYCAZ accordingly.

Please see additional Important Safety Information throughout.
Please also see full enclosed Prescribing Information.

Ceftazidime/Avibactam Susceptibility Testing Devices

MIC Test Strips: Liofilchem®

Description	Catalog Number
Ceftazidime/Avibactam (10 strips/box) - 0.016/4-256/4 µ g/mL	921391
Ceftazidime/Avibactam (30 strips/box) - 0.016/4-256/4 µ g/mL	92139
Ceftazidime/Avibactam (100 strips/box) - 0.016/4-256/4 µ g/mL	921390

For further information or purchase orders, contact Liofilchem at orders@liofilchem.us, call (781) 902-0312, or visit <https://www.liofilchem.com/en-us/>.

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

Liofilchem is a registered trademark of LIOFILCHEM s.r.l.

VITEK® 2 Gram-negative Susceptibility Card: bioMérieux

Description	Catalog Number
AST-N800 (20 cards)	423310
AST-XN09 (20 cards)	423425

- Laboratories must have the latest version of VITEK 2 software to utilize the AST-N800 and AST-XN09 cards. Contact bioMérieux at (800) 682-2666 for information about software for VITEK 2.

ETEST® Strip: bioMérieux

Description	Catalog Number
ETEST Ceftazidime/Avibactam (30 strips) MIC range: ceftazidime 0.016-256 µ g/mL, avibactam 4 µ g/mL	419046

For more information, visit www.biomerieux-usa.com, or call Customer Service at (800) 682-2666. To order, please visit www.biomerieuxDIRECT.com.

VITEK is a registered trademark belonging to bioMérieux SA or one of its subsidiaries.

ETEST is a registered trademark of bioMérieux SA or one of its subsidiaries.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

- Serious and occasionally fatal hypersensitivity (anaphylactic) reactions and serious skin reactions have been reported in patients receiving beta-lactam antibacterial drugs. Before therapy with AVYCAZ is instituted, careful inquiry about previous hypersensitivity reactions to other cephalosporins, penicillins, or carbapenems should be made. Exercise caution if this product is to be given to a penicillin or other beta-lactam-allergic patient because cross sensitivity among beta-lactam antibacterial drugs has been established. Discontinue the drug if an allergic reaction to AVYCAZ occurs.

Please see additional Important Safety Information throughout.
Please also see full enclosed Prescribing Information.

Ceftazidime/Avibactam Susceptibility Testing Devices

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

Description	Available Dilutions in µg/mL	Qty	Reference
Neg MIC 53	• Ceftazidime/Avibactam 4/4-16/4	20 panels	B1017-432
Neg MIC 54	• Ceftazidime/Avibactam 4/4-16/4	20 panels	B1017-433
Neg/Urine Combo 86	• Ceftazidime/Avibactam 8/4-16/4	20 panels	B1017-436
Neg/Urine Combo 88	• Ceftazidime/Avibactam 8/4-16/4	20 panels	B1017-438

Contact your Beckman Coulter Representative or dial (800) 677-7226 for technical microbiology information. Call (800) 526-3821 for Beckman Coulter Customer Service. Visit www.beckmancoulter.com for more information.

MicroScan is a registered trademark of Beckman Coulter, Inc.

BD Phoenix™ Emerge™ Gram-negative Susceptibility Panels: Becton Dickinson

Description	Qty	Reference
BD Phoenix Emerge NMIC-305	25	449294
BD Phoenix Emerge NMIC-306	25	449292
BD Phoenix Emerge NMIC-311	25	449452

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

- *Clostridium difficile*-associated diarrhea (CDAD) has been reported for nearly all systemic antibacterial drugs, including AVYCAZ, and may range in severity from mild diarrhea to fatal colitis. Careful medical history is necessary because CDAD has been reported to occur more than 2 months after the administration of antibacterial drugs. If CDAD is suspected or confirmed, antibacterials not directed against *C. difficile* should be discontinued, if possible.
- Seizures, nonconvulsive status epilepticus (NCSE), encephalopathy, coma, asterixis, neuromuscular excitability, and myoclonia have been reported in patients treated with ceftazidime, particularly in the setting of renal impairment. Adjust dosing based on CrCl.
- Prescribing AVYCAZ in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Please see additional Important Safety Information throughout.
Please also see full enclosed Prescribing Information.

Ceftazidime/Avibactam Susceptibility Testing Devices

BD Sensi-Disc™: Becton Dickinson

Description	Catalog Number
BD Sensi-Disc Ceftazidime/Avibactam 30 µg/20 µg	232218

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.

Susceptibility Testing through Laboratory Specialist, Inc. (LSI)

- Simply call the reference lab service (LSI) at 1.844.835.4458 or request isolate testing by email at info@labspec.org
- An isolate collection kit will be shipped by next-day service with a prepaid completed air bill for your convenience
- Ceftazidime/Avibactam MIC testing will be performed according to Clinical and Laboratory Standards Institute (CLSI) broth microdilution method and results will be sent by fax or email within two days following receipt of the isolate(s)

IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS

Adult cIAI, cUTI and HABP/VABP Patients:

The most common adverse reactions in adult patients with cIAI (≥ 5% when used with metronidazole) were diarrhea (8%), nausea (7%), and vomiting (5%). The most common adverse reactions in adult patients with cUTI (3%) were diarrhea and nausea. The most common adverse reactions in adult patients with HABP/VABP (≥ 5%) were diarrhea (15%) and vomiting (6%).

Pediatric cIAI and cUTI Patients:

The most common adverse reactions in pediatric patients with cIAI and cUTI (>3%) were vomiting, diarrhea, rash, and infusion site phlebitis.

Please see additional Important Safety Information throughout.
Please also see full enclosed Prescribing Information.

Other Diagnostics

T2 Biosystems (direct from blood)

Description	Targets Detected	Qty	Catalog Number
T2Bacteria Panel Cartridge Kit	<i>E. coli</i> , <i>S. aureus</i> , <i>K. pneumoniae</i> , <i>P. aeruginosa</i> , <i>E. faecium</i>	12 cartridges	90-08071
T2Bacteria Panel Reagent Kit		12 reagents	80-07342
T2Resistance Panel Cartridge Kit	<i>mecA/C</i> , <i>vanA/B</i> , CTXM-14/15 KPC, OXA-48 Group, NDM, VIM,	12 cartridges	90-09663
T2Resistance Panel Reagent Kit	IMP, AmpC (CMY/DHA)	12 reagents	80-09810

For more information or to order, please contact your T2 Biosystems Representative, info@t2biosystems.com, or call 877.504.T2T2, option 4.

The use of the T2Bacteria Panel and T2Resistance Panel requires installation and use of the T2Dx Instrument. Panels also require both cartridges and reagents.

BioFire® FilmArray® Pneumonia Panel

Description	Qty	Part Number
BioFire Pneumonia Panel Reagent Kit	30 pouches	RFIT-ASY-0144
BioFire Pneumonia Panel Reagent Kit	6 pouches	RFIT-ASY-0145

For more information or to order, please visit biofiredx.com, contact your BioFire Representative, sales@biofiredx.com, or call 801.736.6354, option 2.

IMPORTANT SAFETY INFORMATION CONTRAINDICATIONS

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Other Diagnostics

Accelerate PhenoTest™ BC kit: Accelerate Diagnostics, Inc.

Description	Qty	Catalog Number
Accelerate PhenoTest™ BC kit	5 kits	10101018

For more information or to order, please contact your Accelerate Diagnostics Representative, accelerate.orders@axdx.com, or call 888.844.6399.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

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