

AVYCAZ[®] dosing recommendations for adult and pediatric patients*



Vial shown not actual size

*In patients at least 31 weeks gestational age with cIAI, cUTI, or HABP/VABP. See designated susceptible pathogens below.

DOSING • ADMINISTRATION

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 (at least 31 weeks gestational age) 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 (ceftazidime and avibactam) is indicated for the treatment of complicated urinary tract infections (cUTI) including pyelonephritis in adult and pediatric patients (at least 31 weeks gestational age) 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 (ceftazidime and avibactam) is indicated for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) in adult and pediatric patients (at least 31 weeks gestational age) 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 only to treat or prevent 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 see full [Prescribing Information](#).

Avycaz[®]
ceftazidime and avibactam
for injection (2.5 g)

Dosing of AVYCAZ® in adult patients with cIAI, cUTI, or HABP/VABP¹



DOSAGE OF AVYCAZ BY INDICATION IN ADULT PATIENTS WITH NORMAL RENAL FUNCTION (CREATININE CLEARANCE >50 mL/min)¹

INFECTION	DOSE	FREQUENCY	INFUSION TIME (HOURS)	DURATION OF TREATMENT
cIAI*	2.5 grams (ceftazidime 2 grams and avibactam 0.5 grams)	Every 8 hours	2	cIAI: 5 to 14 days
cUTI†				cUTI: 7 to 14 days
HABP/VABP				HABP/VABP: 7 to 14 days

*For treatment of cIAI, metronidazole should be given concurrently.

†Including pyelonephritis.

cIAI, complicated intra-abdominal infection; cUTI, complicated urinary tract infection; HABP/VABP, hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia.

See page 4 for dosing in adult patients with renal impairment.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

- In a Phase 3 cIAI 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 see full [Prescribing Information](#).

Dosage of AVYCAZ® in patients aged 2 to 18 years with eGFR >50 mL/min/1.73 m² and in patients aged <2 years without renal impairment

PEDIATRIC DOSE IS CALCULATED BASED ON AGE AND WEIGHT AND ADMINISTERED EVERY 8 HOURS BY IV INFUSION OVER 2 HOURS



INFECTION	AGE RANGE	DOSE	FREQUENCY	INFUSION TIME (HOURS)	DURATION OF TREATMENT
cIAI,* cUTI including pyelonephritis, and HABP/VABP	2 years to less than 18 years [†]	AVYCAZ 62.5 mg/kg to a maximum of 2.5 grams (ceftazidime 50 mg/kg and avibactam 12.5 mg/kg to a maximum dose of ceftazidime 2 grams and avibactam 0.5 grams)	Every 8 hours	2	cIAI: 5 to 14 days cUTI: 7 to 14 days HABP/VABP: 7 to 14 days
	6 months to less than 2 years	AVYCAZ 62.5 mg/kg (ceftazidime 50 mg/kg and avibactam 12.5 mg/kg)			
	3 months to less than 6 months	AVYCAZ 50 mg/kg (ceftazidime 40 mg/kg and avibactam 10 mg/kg)			
	Greater than 28 days [‡] to less than 3 months	AVYCAZ 37.5 mg/kg (ceftazidime 30 mg/kg and avibactam 7.5 mg/kg)			
	Less than or equal to 28 days [§] with GA 31 weeks and older	AVYCAZ 25 mg/kg (ceftazidime 20 mg/kg and avibactam 5 mg/kg)			

*AVYCAZ was used in conjunction with metronidazole 10 mg/kg intravenously every 8 hours in pediatric cIAI patients.

[†]For pediatric patients (aged 2 years and older) with eGFR less than or equal to 50 mL/min/1.73 m², dosage adjustments are recommended.

[‡]Includes full-term infants with PNA >28 days and pre-term infants with corrected age >28 days. Corrected age is calculated by subtracting the number of weeks born before 40 weeks of gestation from the PNA.

[§]Includes neonates PNA ≤28 days and pre-term infants with corrected age ≤28 days.

cIAI, complicated intra-abdominal infection; cUTI, complicated urinary tract infection; eGFR, estimated glomerular filtration rate; GA, gestational age; HABP/VABP, hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia; IV, intravenous; PNA, postnatal age.

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 see full [Prescribing Information](#).



Dosing in adult patients with renal impairment¹



DOSAGE ADJUSTMENTS IN ADULT PATIENTS WITH RENAL IMPAIRMENT¹

ESTIMATED CREATININE CLEARANCE (mL/min)*	DOSE FOR AVYCAZ® (CEFTAZIDIME and AVIBACTAM)†	FREQUENCY
31 to 50	AVYCAZ 1.25 grams (ceftazidime 1 gram and avibactam 0.25 grams) intravenously	Every 8 hours
16 to 30	AVYCAZ 0.94 grams (ceftazidime 0.75 grams and avibactam 0.19 grams) intravenously	Every 12 hours
6 to 15	AVYCAZ 0.94 grams (ceftazidime 0.75 grams and avibactam 0.19 grams) intravenously	Every 24 hours
≤5‡	AVYCAZ 0.94 grams (ceftazidime 0.75 grams and avibactam 0.19 grams) intravenously	Every 48 hours

*As calculated using the Cockcroft-Gault formula.

†All doses of AVYCAZ are administered over 2 hours.

‡Both ceftazidime and avibactam are hemodialyzable; thus, administer AVYCAZ after hemodialysis on hemodialysis days.

- Monitor CrCl at least daily in adult patients with changing renal function and adjust the dosage of AVYCAZ accordingly¹
- No dosing adjustment is necessary for AVYCAZ in patients with impaired hepatic function¹

CrCl, creatinine clearance.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

- *Clostridioides 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.

Avycaz[®]
ceftazidime and avibactam
for injection (2.5 g)

Dosing in pediatric patients with renal impairment¹



DOSAGE ADJUSTMENTS IN PEDIATRIC PATIENTS 2 YEARS AND OLDER WITH RENAL IMPAIRMENT*¹

ESTIMATED eGFR [†] (mL/min/1.73 m ²)	DOSE FOR AVYCAZ [®] (CEFTAZIDIME and AVIBACTAM) [‡]	FREQUENCY
31 to 50	AVYCAZ 31.25 mg/kg to a maximum of 1.25 grams (ceftazidime 25 mg/kg and avibactam 6.25 mg/kg to a maximum dose of ceftazidime 1 gram and avibactam 0.25 grams)	Every 8 hours
16 to 30	AVYCAZ 23.75 mg/kg to a maximum of 0.94 grams (ceftazidime 19 mg/kg and avibactam 4.75 mg/kg to a maximum dose of ceftazidime 0.75 grams and avibactam 0.19 grams)	Every 12 hours
6 to 15 [§]	AVYCAZ 23.75 mg/kg to a maximum of 0.94 grams (ceftazidime 19 mg/kg and avibactam 4.75 mg/kg to a maximum dose of ceftazidime 0.75 grams and avibactam 0.19 grams)	Every 24 hours
≤5 [§]	AVYCAZ 23.75 mg/kg to a maximum of 0.94 grams (ceftazidime 19 mg/kg and avibactam 4.75 mg/kg to a maximum dose of ceftazidime 0.75 grams and avibactam 0.19 grams)	Every 48 hours

*Dosing was derived based on the population PK modeling, which assumed similar proportional effects of renal impairment in adults and pediatric patients 2 years and older.

[†]As calculated using the Schwartz bedside formula.

[‡]All doses of AVYCAZ are administered over 2 hours.

[§]Both ceftazidime and avibactam are hemodialyzable; thus, administer AVYCAZ after hemodialysis on hemodialysis days.

eGFR, estimated glomerular filtration rate; PK, pharmacokinetic.

- There is insufficient information to recommend a dosing regimen for pediatric patients <2 years of age with renal impairment
- Monitor eGFR at least daily in pediatric patients with changing renal function and adjust the dosage of AVYCAZ accordingly

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

- 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 or a prophylactic indication 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 see full [Prescribing Information](#).





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IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS

Adult cIAI, cUTI, and HABP/VABP Patients

The most common adverse reactions in adult patients with cIAI ($\geq 5\%$ 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 ($\geq 5\%$) were diarrhea (15%) and vomiting (6%).

Pediatric Patients

The most common adverse reactions ($>3\%$) in pediatric patients aged 3 months and older were vomiting, diarrhea, rash, and infusion site phlebitis.

The most common adverse reactions ($>3\%$) in pediatric patients less than 3 months of age were vomiting and increased transaminases.

Please see additional Important Safety Information throughout. Please see full [Prescribing Information](#).

Reference: 1. AVYCAZ[®] (ceftazidime and avibactam) [prescribing information]. North Chicago, IL: AbbVie, Inc.

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