

Avycaz® (ceftazidime/avibactam) – Expanded indication

- On December 20, 2022, the [FDA approved](#) Allergan’s [Avycaz \(ceftazidime/avibactam\)](#) injection, for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) in adult and pediatric patients aged 3 months and older caused by the following susceptible gram-negative microorganisms: *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Escherichia coli*, *Serratia marcescens*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, and *Haemophilus influenzae*.
 - Avycaz was previously approved for this indication in adults 18 years of age and older.
- Avycaz is also approved for adult and pediatric patients aged 3 months and older for the treatment of complicated intra-abdominal infections (cIAI), used in combination with metronidazole; and complicated urinary tract infections (cUTI), including pyelonephritis.
- The safety and effectiveness of Avycaz in the treatment of cUTI, cIAI, and HABP/VABP have been established in pediatric patients aged 3 months to less than 18 years. Use of Avycaz is supported by evidence from adequate and well-controlled studies of Avycaz in adults with cUTI, cIAI, and HABP/VABP and additional pharmacokinetic and safety data from pediatric trials.
- The recommended dose of Avycaz in all indications for pediatric patients aged 2 years to less than 18 years and an estimated glomerular filtration rate > 50 mL/min/1.73 m² and in pediatric patients aged 3 months to less than 2 years without renal impairment is described in the table below:
 - Avycaz is administered every 8 hours by intravenous infusion over 2 hours.
 - Refer to the Avycaz drug label for dosing for all its other indications in adults.

Age Range	Dose	Duration of Treatment
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)	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)	