

Avycaz® (ceftazidime/avibactam) – Expanded indications

- On January 26, 2024, the <u>FDA approved</u> AbbVie's <u>Avycaz (ceftazidime/avibactam)</u> for the
 pediatric population from birth (at least 31 weeks gestational age) for the treatment of complicated
 intraabdominal infections (cIAI); complicated urinary tract infections (cUTI), including
 pyelonephritis; and hospital-acquired bacterial pneumonia and ventilator-associated bacterial
 pneumonia (HABP/VABP).
 - Avycaz was previously approved for these indications in pediatric patients aged 3 months and older.
- The approval of Avycaz for the expanded indications was 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 most common adverse reactions (> 3%) with Avycaz use in pediatric patients less than 3 months of age were vomiting and increased transaminases.
- The recommended dose of Avycaz for the treatment of pediatric patients greater than 28 days to
 less than 3 months is 37.5 mg/kg every 8 hours via intravenous (IV) infusion. In pediatric patients
 less than or equal to 28 days with gestational age of at least 31 weeks, the recommended dose is
 25 mg/kg every 8 hours via IV infusion. The duration of treatment ranges from 5 to 14 days,
 depending on the infection.
 - Refer to the Avycaz drug label for complete dosing and administration recommendations.



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