

Cresemba® (isavuconazonium) - Expanded indication

- On December 8, 2023, <u>Astellas announced</u> the FDA approval of <u>Cresemba (isavuconazonium)</u>, for the treatment of invasive aspergillosis (IA) and invasive mucormycosis (IM) in pediatric patients.
 - Cresemba injection is approved for treatment of IA and IM in adults and pediatric patients
 1 year of age and older.
 - Cresemba capsules are approved for treatment of IA and IM in adults and pediatric patients 6 years of age and older who weigh 16 kg and greater.
- Cresemba was previously approved for these indications in adults only.
- The approval of Cresemba for the expanded indication for IA was supported by evidence from one adequate and well-controlled trial in adult patients and additional pharmacokinetic and safety data in pediatric patients 1 year of age and older. Adverse reactions in this pediatric population were similar to those reported in the adult population.
- The approval of Cresemba for the expanded indication for IM is supported by one open-label trial
 in adult patients with IM, a retrospective review of survival data for adult patients with untreated
 IM, and additional pharmacokinetic and safety data in pediatric patients 1 year of age and older.
 Adverse reactions in this pediatric population were similar to those reported in the adult
 population.
- The most common adverse reactions with Cresemba use in pediatric patients were diarrhea, abdominal pain, vomiting, elevated liver chemistry tests, rash, nausea, pruritus, and headache.
- Refer to the Cresemba drug label for pediatric and adult dosing for IA and IM.



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