



## Eraxis® (anidulafungin) – Expanded indication

- On September 22, 2020, the [FDA approved](#) Pfizer's [Eraxis \(anidulafungin\)](#), for the treatment of candidemia and the following *Candida* infections: intra-abdominal abscess and peritonitis in adults and pediatric patients 1 month of age and older.
  - Eraxis was previously approved for this indication in adults only.
  - Eraxis has not been studied in adult and pediatric patients with endocarditis, osteomyelitis, and meningitis due to *Candida*, and has not been studied in sufficient numbers of neutropenic patients to determine efficacy in this group. The dosage of Eraxis for the treatment of *Candida* dissemination into the central nervous system and the eye has not been established.
- Eraxis is also approved for the treatment of esophageal candidiasis in adults.
- The approval of Eraxis for the expanded indication was based on an open-label, non-comparative study in 68 pediatric patients aged 1 month to < 18 years with candidemia/invasive candidiasis. Patients received once daily intravenous (IV) Eraxis followed by an optional switch to oral [fluconazole](#) up to day 49. A successful global response was defined as having both successful clinical (cure or improvement) and microbiological (eradication or presumed eradication) response.
  - The overall rates of successful global response were 70.3% (95% CI: 57.6, 81.1) and 71.9% (95% CI: 59.2, 82.4) at the end of IV treatment and end of treatment, respectively.
- The most common adverse reactions ( $\geq 5\%$ ) with Eraxis use in pediatric patients were diarrhea, vomiting, pyrexia, abdominal pain, anemia, thrombocytopenia, increased alanine aminotransferase and aspartate aminotransferase, hypoglycemia, epistaxis, and rash.
- The recommended dose of Eraxis for the treatment Candidemia and other *Candida* infections in pediatric patients is a single IV loading dose of 3 mg/kg (not to exceed 200 mg) on day 1, followed by a once daily IV maintenance dose of 1.5 mg/kg (not to exceed 100 mg) thereafter. Overall antifungal treatment should continue for at least 14 days after the last positive culture.
  - Refer to the Eraxis drug label for dosing in adult patients.



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