Mycamine® (micafungin) – Expanded indication

- On December 20, 2019, the FDA approved Astellas's Mycamine (micafungin), for the treatment of candidemia, acute disseminated candidiasis, *Candida* peritonitis and abscesses without meningoencephalitis and/or ocular dissemination in pediatric patients younger than 4 months of age.
    - The safety and effectiveness of Mycamine have not been established for the treatment of candidemia with meningoencephalitis and/or ocular dissemination in pediatric patients younger than 4 months of age as a higher dose may be needed.
    - Mycamine has not been adequately studied in patients with endocarditis, osteomyelitis and meningoencephalitis due to *Candida*.
    - The efficacy of Mycamine against infections caused by fungi other than *Candida* has not been established.
- Mycamine is also approved in adult and pediatric patients 4 months of age and older for:
    - Treatment of candidemia, acute disseminated candidiasis, *Candida* peritonitis and abscesses
    - Treatment of esophageal candidiasis
    - Prophylaxis of *Candida* infections when undergoing hematopoietic stem cell transplantation.
- This use and dosage of Mycamine for the expanded indication are supported by evidence from adequate and well-controlled studies in adult and pediatric patients 4 months of age and older with additional pharmacokinetic and safety data in pediatric patients younger than 4 months of age.
- The most common adverse reactions (≥ 15%) with Mycamine use in pediatric patients younger than 4 months of age were sepsis, acidosis, anemia, oxygen saturation decreased and hypokalemia.
- The recommended dose of Mycamine for pediatric patients younger than 4 months of age for treatment of candidemia, acute disseminated candidiasis, *Candida* peritonitis and abscesses without meningoencephalitis and/or ocular dissemination is 4 mg/kg once daily via intravenous infusion.
- Refer to the Mycamine drug label for dosing for all its other indications.