INDICATIONS AND USAGE

MYCAMINE (micafungin for injection) is indicated for:

- Treatment of candidemia, acute disseminated candidiasis, *Candida* peritonitis and abscesses in adult and pediatric patients 4 months of age and older.
- 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.
- Treatment of esophageal candidiasis in adult and pediatric patients 4 months and older.
- Prophylaxis of *Candida* infections in adult and pediatric patients 4 months of age and older undergoing hematopoietic stem cell transplantation (HSCT).

Limitations of Use

- 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.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

MYCAMINE is contraindicated in persons with known hypersensitivity to micafungin, any component of MYCAMINE, or other echinocandins.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions: Isolated cases of serious hypersensitivity (anaphylaxis and anaphylactoid) reactions (including shock) have been reported in patients receiving MYCAMINE. If these reactions occur, MYCAMINE should be discontinued and appropriate treatment administered.

Hematological Effects: Cases of acute intravascular hemolysis, hemolytic anemia, and hemoglobinuria have been reported. Patients who develop clinical or laboratory evidence of hemolysis or hemolytic anemia should be monitored closely for evidence of worsening of these conditions and evaluated for the risk/benefit of continuing MYCAMINE therapy.

Hepatic Effects: In some patients with serious underlying conditions who were receiving MYCAMINE along with multiple concomitant medications, clinical hepatic abnormalities have occurred, and isolated cases of significant hepatic impairment, hepatitis, and hepatic failure have been reported. Patients who develop abnormal liver function tests should be monitored for evidence of worsening hepatic function and evaluated for the risk/benefit of continuing MYCAMINE therapy.

Renal Effects: Elevations in BUN and creatinine, and isolated cases of significant renal impairment or acute renal failure have been reported. Patients who develop abnormal renal function tests should be monitored for worsening renal function.

Infusion and Injection Site Reactions: Possible histamine-mediated symptoms have been reported with MYCAMINE, including rash, pruritus, facial swelling, and vasodilatation. Slow the infusion rate if infusion reaction occurs. Injection site reactions, including phlebitis and thrombophlebitis have been reported at MYCAMINE doses of 50 to 150 mg/day, and tended to occur more often with peripheral intravenous administration.

ADVERSE REACTIONS

The most common adverse reactions across adult and pediatric clinical trials for all indications included diarrhea, nausea, vomiting, abdominal pain, pyrexia, thrombocytopenia, neutropenia, and headache.

In pediatric patients younger than 4 months of age, the following additional common adverse reactions were reported at an incidence rate of ≥15%: sepsis, acidosis, anemia, oxygen saturation decreased, and hypokalemia.