

Micagin™

Micafungin Sodium

Presentation

Micagin™ IV Infusion: Each vial contains Micafungin Sodium USP equivalent to Micafungin 50 mg.

Description

Micagin is a sterile, lyophilized product for intravenous (IV) infusion that contains Micafungin Sodium. Micafungin sodium is a semisynthetic lipopeptide (echinocandin). Micafungin inhibits the synthesis of 1,3-β-D-glucan, an integral component of the fungal cell wall, which is not present in mammalian cell.

Indications and Usage

- Treatment of patients with Candidemia, Acute Disseminated Candidiasis, Candida Peritonitis and Abscesses
- Treatment of patients with Esophageal Candidiasis
- Prophylaxis of Candida Infections in patients undergoing Hematopoietic stem cell transplantation

Dosage and administration

Use in children ≥ 4 months of age and elderly

Indication	Dose	
	Body weight > 40 kg	Body weight ≤ 40 kg
Treatment of invasive candidiasis	100 mg/day	2 mg/kg/day
Treatment of oesophageal candidiasis(only for patients ≥ 16 years of age)	150 mg/day	3 mg/kg/day
Prophylaxis of Candida infection	50 mg/day	1 mg/kg/day

Use in children (including neonates) < 4 months of age

Indication	Dose
Treatment of invasive candidiasis	4 -10 mg/kg/day
Prophylaxis of Candida infection	2 mg/kg/day

No loading dose is required.

Instruction for use

- Aseptically add 5mL of 0.9% Sodium Chloride from supplied 100 ml bottle of 0.9% Sodium Chloride to vial containing Micagin lyophilized powder.
- Gently dissolve the powder by swirling the vial. DO NOT VIGOROUSLY SHAKE THE VIAL. Visually inspect for particulate matter. Do not use material if there is any evidence of precipitation of foreign matter.
- Transfer the freshly prepared solution to the 100 ml vial containing 0.9 % Sodium Chloride solution for further infusion.
- Use as necessary. Do not store the reconstituted solution more than 24 hours.
- Micagin should be administered by intravenous infusion only. Infuse over one hour. More rapid infusion may result in more frequent histamine mediated reactions.

Use in pregnancy and lactation

There is no adequate and well-controlled studies of Micafungin in pregnant women. Micafungin should be used in pregnancy only if potential benefit justifies the potential risk to the fetus.

It is not known whether Micafungin is excreted in human milk. Caution should be exercised when Micagin is administered to a nursing mother.

Side effects

- Most common side effects include Diarrhea, Nausea, Vomiting, Pyrexia, Hypokalemia, Thrombocytopenia and Headache.
- Histamine-mediated symptoms like Rash, Pruritus, Facial Swelling and Vasodilation.

Contraindications

Micagin is contraindicated in patients with known hypersensitivity to Micafungin, any component of Micagin or other Echinocandins.

Precautions

- If anaphylaxis and anaphylactoid reactions occur discontinue Micagin and administer appropriate treatment.
- Isolated cases of acute intravascular hemolysis, hemolytic anemia and hemoglobinuria have been reported. Monitor closely those patients and evaluate risk/benefit of continuing Micagin therapy.
- Monitor closely patients who develop abnormalities in liver function test (like Hepatic Dysfunction, Hepatitis, and Hepatic Failure) and evaluate risk/benefit of continuing Micagin therapy.
- Monitor closely patients with renal dysfunction and acute renal failure.

Drug interactions

Monitor for Sirolimus, Itraconazole or Nifedipine toxicity and dosage of Sirolimus, Itraconazole or Nifedipine should be reduced, if necessary.

Overdose

Micafungin is highly protein bound, therefore, is not dialyzable. No case of Micafungin over dosage has been reported. Repeated daily doses up to 8mg/kg (maximum total dose of 896 mg) in adult patients have been administered in clinical trials with no reported dose-limiting toxicity.

Storage

Before Reconstitution: Do not store above 30 °C. Keep away from light and out of the reach of children.

After Reconstitution: Do not store the reconstituted solution above 30 °C. The diluted infusion should be protected from light and may be stored for up to 24 hours at room temperature.

Commercial Pack

Micagin™ IV Infusion: Each box contains one vial containing 50 mg Micafungin lyophilized powder or cake, one 5 ml sterile disposable syringe, one bottle of 100 ml 0.9% Sodium Chloride, one infusion set, a hanger, first aid band and alcohol pad.