MONOGRAPH

Micafungin Monograph - Paediatric

Scope (Staff):	Medical, Pharmacy, Nursing
Scope (Area):	All Clinical Areas

Child Safe Organisation Statement of Commitment

CAHS commits to being a child safe organisation by applying the National Principles for Child Safe Organisations. This is a commitment to a strong culture supported by robust policies and procedures to reduce the likelihood of harm to children and young people.

This document should be read in conjunction with this DISCLAIMER

QUICKLINKS

Dosage/Dosage Adjustments	Administration	Compatibility	Monitoring

DRUG CLASS

Echinocandin antifungal.[1-3]

INDICATIONS AND RESTRICTIONS

IV: Monitored (orange) antifungal

- If the use is consistent with a standard approved indication, this must be communicated to ChAMP by documenting that indication on all prescriptions (inpatient and outpatient).
- The ChAMP team will review if ongoing therapy is required and/or if the order does not meet ChAMP Standard Indications
- If use is not for a standard approved indication, phone approval must be obtained from ChAMP before prescribing.

Micafungin is active against *Candida* spp. (fungicidal) and *Aspergillus* spp. (fungistatic).[2, 4]

It is indicated in the treatment of invasive candidiasis and prophylaxis for fungal infections in immunosuppressed patients.[2, 3] Refer to ChAMP Antifungal Prophylaxis guidelines for specific prophylaxis indications.

CONTRAINDICATIONS

- Hypersensitivity to micafungin, other echinocandin antifungals or any component of the formulation.[2, 5-7]

PRECAUTIONS

- The incidence of some adverse events (itch, liver dysfunction, hyperbilirubinaemia, fever or infusion related reactions) from micafungin is higher in the paediatric population than in adults.[3]
- Micafungin should be used with caution in patients with hepatic diseases due to the increased risk of liver function test derangement.[3, 5, 6]
- Micafungin should be used with caution in patients with renal disease or impairment due to the risk of additive renal dysfunction and/or acute renal failure.[3, 5, 6]
- Infusion and injection site related reactions have been reported with the administration of micafungin and are more common when administered via a peripheral line. These reactions may be reduced by slowing the infusion rate and/or infusing solutions at concentrations of 1.5 mg/mL or greater via a central catheter.[3, 5, 6]

FORMULATIONS

Listed below are products available at PCH, other formulations may be available, check with pharmacy if required:

- 50 mg powder for injection vial

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Neonates (< 4 weeks):

Treatment of invasive candidiasis:

Birth (at term) and < 4 weeks of age: 10 mg/kg/dose 24 hourly.[3, 7-10]

Doses up to 15 mg/kg/day may be considered for central nervous system (CNS) infections due to poor penetration of micafungin into the CNS.[9, 10] Discuss with Infectious Diseases.

Safety and efficacy studies have been done in preterm neonates from 25 weeks gestational age for treatment. Contact Infectious Diseases for advice.[9, 10]

Prophylaxis:

Birth (at term) and < 4 weeks of age: 2 mg/kg/dose once daily.[3, 11]

There is limited information regarding the appropriate prophylaxis dosing for pre-term neonates. Contact Infectious Diseases for advice.

Children ≥ 4 weeks:

Treatment of invasive candidiasis:

Children ≥ 4 weeks to < 4 months of age: 10 mg/kg/dose (to a maximum of 100 mg) 24 hourly.[3]

Children ≥ 4 months of age and ≤ 40 kg: 2 mg/kg/dose once daily.[3] Consider increasing dose to 4 mg/kg/dose (to a maximum of 160 mg) once daily for confirmed invasive Candidiasis or if inadequate response.[3, 5, 11]

Children > 40 kg: 100 mg once daily.[11]

200 mg once daily may be considered if response is inadequate.[2, 3]

Prophylaxis:

Children ≥ 4 weeks to < 4 months of age: 2 mg/kg/dose once daily.[3, 11]

Children ≥ 4 months of age: 1 mg/kg/dose (to a maximum of 50 mg) once daily.[5, 11]

Dosing in Overweight and Obese Children: Dose based on actual body weight. Limited data suggests that micafungin clearance increases as weight increases. Higher doses may be necessary in obese children.[3]

Renal impairment:

- No specific dose adjustments are required in renal impairment. Micafungin should be used with caution in patients with renal impairment as renal function may deteriorate.[3, 6, 12]

Hepatic impairment:

- No specific dose adjustments are required in hepatic impairment; however care should be taken in patients with hepatic impairment due to the risk of hepatotoxicity. [3, 6, 12]

RECONSTITUTION & ADMINISTRATION

Reconstitution:

- To reconstitute a vial of micafungin powder for injection use 5 mL of either sodium chloride 0.9% or glucose 5% slowly injected along the side of each vial to reduce the risk of foaming. Slowly rotate the vial to dissolve the powder – Do NOT shake the vial. [1, 5]

Vial	Volume of sodium chloride 0.9% or glucose 5% to add[1, 6]	Resulting concentration
50 mg	5 mL	10 mg/mL

Administration:

- After reconstitution, micafungin must be further diluted to a final concentration of 0.5 to 4 mg/mL with compatible fluid and infused over at least 60 minutes.[1-3, 5, 11]
- Faster infusion times are associated with an increased incidence of infusion related reactions.[3]
- Concentrations ≥1.5 mg/mL **must** be administered via a central line.[1, 4, 11]

- Solutions in syringes or bags should be protected from light during storage. It is not necessary to protect the administration tubing from light.[1, 5, 6]

Hospital in the Home (HiTH) Administration:

- Oncology patients requiring long term micafungin via HiTH may be suitable for administration of micafungin via Springfusor® device at the discretion of the treating consultant.
- The minimum dose that may be administered via a Springfusor® is 5 mg. Doses greater than 45 mg require central access due to the concentrations required for the Springfusor® device.
- The final dose must be prepared to a final volume of either 10 mL or 30 mL to allow administration over 60 minutes via the rate control tubing. Refer to the table below:

Central access		Peripheral access	
Dose range	**Syringe size**	**Dose range**	**Syringe size**
≥ 15 mg to ≤ 50 mg	30 mL Braun Syringe	≥ 15 mg to ≤ 45 mg	30 mL Braun Syringe
≥ 5 mg to ≤ 15 mg	10 mL Braun Syringe	≥ 5 mg to ≤ 15 mg	10 mL Braun Syringe

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

Compatible fluids:

- Glucose 5%
- Sodium chloride 0.9%[1, 7]

Compatible at Y-site:

Compatibilities of IV drugs must be checked when two or more drugs are given concurrently.

MONITORING

- Liver function, renal function tests and full blood picture should be completed at baseline and weekly throughout treatment. The frequency of testing should be increased in patients who develop altered renal or hepatic function tests.[3, 5, 12]

ADVERSE EFFECTS

Common: increased bilirubin, headache, anxiety, nausea, vomiting, diarrhoea, rash, pruritis, hypokalaemia, anaemia, thrombocytopenia, neutropenia, leucocytosis, thrombocytosis, increased liver enzymes, phlebitis, infusion related reactions (fever, flushing, hypotension, chills, rash, urticaria, itch, bronchospasm, dyspnoea).[2, 5, 12]

Infrequent: electrolyte disturbances (hypomagnesemia and hypocalcaemia), haemolysis, haemolytic anaemia.[2, 5, 12]

Rare: hepatotoxicity, renal impairment, severe cutaneous adverse reactions (SCARs), anaphylaxis, anxiety, decreased appetite, arrhythmias, disseminated intravascular coagulation, confusion, dizziness, tremors, pancytopenia, eosinophilia, leucopenia, hyperhidrosis.[2, 5, 12]

STORAGE

- Powder for injection vials should be stored below 25 °C.[1, 3, 13]
- Products prepared by Pharmacy Compounding Service (PCS) should be stored below 25°C, not refrigerated and protected from light.[1, 12]

INTERACTIONS

This medication may interact with other medications; consult PCH approved references (e.g. Clinical Pharmacology), a clinical pharmacist or PCH Medicines Information Service on extension 63546 for more information.

Please note: The information contained in this guideline is to assist with the preparation and administration of **micafungin**. Any variations to the doses recommended should be clarified with the prescriber prior to administration

Related CAHS internal policies, procedures and guidelines

Antimicrobial Stewardship Policy

ChAMP Empiric Guidelines and Monographs

KEMH Neonatal Medication Protocols

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