### Micafungin Monograph - Paediatric

| Scope (Staff): | Clinical Staff – Medical, Nursing, Pharmacy |
| Scope (Area): | Perth Children’s Hospital (PCH) |

This document should be read in conjunction with this DISCLAIMER

| DESCRIPTION | Micafungin is an echinocandin antifungal. It inhibits 1,3-beta-D-glucan synthesis in the fungal cell wall altering cell membrane permeability.\(^{(1, 2)}\) |
| INDICATIONS AND RESTRICTIONS | Micafungin is active against Candida spp. (fungicidal) and Aspergillus spp. (fungistatic).\(^{(1, 2)}\) |
| | It is indicated in the treatment of invasive candidiasis and prophylaxis of candida infection in immunosuppressed patients (e.g. prolonged neutropenia and/or Haematopoietic Stem Cell Transplant – HSCT).\(^{(1, 3)}\) |
| | 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). |
| | • If use is not for a standard approved indication, phone approval must be obtained from ChAMP before prescribing. |
| | • The ChAMP team will review if ongoing therapy is required and/or if the order does not meet ChAMP Standard Indications. |
| CONTRAINDICATIONS | Micafungin is contraindicated in patients with a hypersensitivity to micafungin or any echinocandin antifungal.\(^{(1-5)}\) |
| 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.\(^{(6)}\) |
| | • Micafungin should be used with caution in patients with hepatic diseases due to the increased risk of elevated liver function tests.\(^{(2, 3, 5)}\) |
| | • 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.\(^{(2, 3, 5)}\) |
| | • Infusion and injection site related reactions have been reported with the administration of micafungin and are more common. |
| FORMULATIONS | Available at PCH:  
- 50mg powder for injection vial  
Other formulations available:  
- 100mg powder for injection vial |
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<tr>
<td>DOSAGE</td>
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- The doses listed below fall within the standard range.  
- Higher doses may be prescribed for certain situations in consultation with an infectious diseases or clinical microbiology consultant.  
**Neonates (less than 30 days of age):**  
**Treatment of invasive candidiasis:**  
**Neonates:** 10mg/kg/dose 24 hourly.\(^{(5, 7-10)}\)  
Doses up to 15mg/kg/day may be considered for CNS infections due to poor penetration of micafungin into the CNS.\(^{(7, 9, 10)}\) Discuss with Infectious Disease clinician.  
Safety and efficacy studies have been done in preterm neonates from 25 weeks gestational age.\(^{(9, 10)}\)  
**Children:**  
**Prophylaxis:**  
**Birth (at term) to < 4 months of age:** 2mg/kg/dose once daily.  
**Children ≥4 month of age:** 1mg/kg/dose (to a maximum of 50mg) once daily.\(^{(1, 5, 6, 11)}\)  
**Treatment of invasive candidiasis:**  
**Children >1 month to <4 months of age:** 10mg/kg/dose (to a maximum of 100mg) 24 hourly.\(^{(5)}\)  
**Children ≥ 4 months of age and <40 kg:** 2 mg/kg/dose once daily.\(^{(5)}\) Consider increasing dose to 4mg/kg/dose once daily for confirmed invasive Candidiasis.\(^{(5)}\)  
**Children >40 kg:** 100 mg once daily.\(^{(1)}\)  
Doses up to 150-200 mg once daily may be considered if response is inadequate or for oesophageal candidiasis.\(^{(1)}\)  
**DOSAGE ADJUSTMENT** |  
- No specific dose adjustments are required in either hepatic or renal impairment, however care should be taken in patients with hepatic impairment due to the risk of hepatotoxicity.\(^{(3-5, 12, 13)}\)  
- Care should also be taken in patients with renal impairment. There have been cases of renal impairment and renal |
**RECONSTITUTION**

To reconstitute a vial of micafungin powder for injection use 5mL of either sodium chloride 0.9% or glucose 5% slowly injected along the side of each vial to reduce the risk of foaming.\(^{(3, 14)}\)

- Slowly rotate the vial to dissolve the powder.
- Do NOT shake the vial.
- The required dose must be further diluted prior to administration.\(^{(2, 3, 14)}\)

<table>
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<tr>
<th>Vial</th>
<th>Volume of sodium chloride 0.9% or glucose 5% to add(^{(14)})</th>
<th>Resulting concentration</th>
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<td>50mg</td>
<td>5mL</td>
<td>10mg/mL</td>
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**ADMINISTRATION**

- After reconstitution, micafungin must be further diluted to a final concentration of 0.5-4mg/mL with compatible fluid and infused over at least 60 minutes.\(^{(2, 3, 14)}\)
- Concentrations ≥1.5mg/mL must be administered via a central line.\(^{(3, 5, 6, 14)}\)
- Solutions in syringes or bags should be protected from light from the time of dilution and during administration. It is not necessary to protect the administration tubing from light.\(^{(2, 5)}\)

**MONITORING**

- Liver function, renal function tests and full blood picture should be completed at baseline and weekly throughout treatment.\(^{(1, 2, 5, 11)}\)

**ADVERSE EFFECTS**

- **Common:** increased bilirubin, headache, nausea, vomiting, diarrhoea, constipation, rash, hypokalaemia, anaemia, thrombocytopenia, rash, increase liver enzymes, injection site reactions, infusion related reactions (fever, flushing, hypotension, chills, rash, urticaria, itch, bronchospasm, dyspnoea).\(^{(1, 11)}\)
- **Rare:** electrolyte disturbances (hypomagnesemia and hypocalcaemia), haemolysis, haemolytic anaemia, hepatic dysfunction, renal impairment, severe cutaneous adverse reactions (SCARs), anaphylaxis, anxiety, decreased appetite, arrhythmias, disseminated intravascular coagulation, confusion, dizziness, tremors, pancytopenia, eosinophilia, leucopenia, thrombocytopenia, hyperhidrosis, pruritus.\(^{(1, 11)}\)

**COMPATIBLE FLUIDS**

- Glucose 5%
- Sodium chloride 0.9%\(^{(14)}\)

**STORAGE**

- Powder for injection vials should be stored below 25 °C.\(^{(4, 14)}\)
- Products prepared by Pharmacy Compounding Service (PCS)
## INTERACTIONS

Micafungin may interact with other medications; please consult PCH approved references (e.g. Clinical Pharmacology), your ward pharmacist or Pharmacy on extension 63546 for more information.

- Micafungin reduces the clearance of ciclosporin (cyclosporine), tacrolimus and sirolimus. Levels should be monitored and doses adjusted accordingly.\(^{(2, 3)}\)
- Micafungin may increase the concentration of itraconazole; the itraconazole dose may need to be reduced.\(^{(2, 3, 11)}\)
- Micafungin may increase the concentration of nifedipine. Consider monitoring for hypotension and reducing the nifedipine dose.\(^{(2, 3)}\)
- Micafungin when prescribed concurrently with corticosteroids increases the risk of leukopenia, neutropenia, anaemia and thrombocytopenia. Use with caution and monitor.\(^{(2)}\)

## COMMENTS

To access the Manufacturer SDS for this product, use the following link to ChemAlert.

**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
References and related external legislation, policies, and guidelines

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<td>Children’s Antimicrobial Management Program</td>
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Healthy kids, healthy communities

[Image]