



## MONOGRAPH

# Anidulafungin Monograph - Paediatric

<b>Scope (Staff):</b>	Medical, Pharmacy, Nursing
<b>Scope (Area):</b>	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.<sup>(1-3)</sup>

### INDICATIONS AND RESTRICTIONS

#### IV: Restricted (red) antifungal

ChAMP approval is required prior to prescription.

- Anidulafungin is indicated in the treatment of invasive candidiasis including candidaemia.<sup>(3, 4)</sup>
- Alternative echinocandin antifungals such as [micafungin](#) for prophylaxis or [caspofungin](#) are generally preferred in paediatric patients at PCH.

### CONTRAINDICATIONS

- Hypersensitivity to anidulafungin, other echinocandins or any component of the formulation.<sup>(1, 3, 5-7)</sup>
- Anidulafungin is contraindicated in patients with hereditary fructose intolerance (HFI) due to the fructose content (119 mg of fructose per vial) of the preparation. Care should be taken in children under 2 years of age as HFI may not have been diagnosed. <sup>(1, 3, 5-8)</sup>

## PRECAUTIONS

- Clinically significant hepatic abnormalities can occur with treatment.<sup>(5)</sup>
- Anidulafungin contains polysorbate 80 which may increase the risk of toxicity in low-birth-weight infants. Toxicity due to polysorbate 80 may present as thrombocytopenia, renal dysfunction, cholestasis, ascites, hypotension or metabolic acidosis. Micafungin is the preferred agent in low-birth-weight.<sup>(1, 5, 6)</sup>

## FORMULATIONS

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

- 100mg powder for reconstitution

Imprest location: [Formulary One](#)

## DOSAGE & DOSAGE ADJUSTMENTS

### Neonates:

- There is minimal information regarding the use of anidulafungin in neonates. Caution should be used in those under 4 weeks of age due to the polysorbate content of the preparation.<sup>(1, 5, 7)</sup>
- Prior to use of anidulafungin in neonates, consideration should be given to the need for central nervous system (CNS) cover. Pharmacokinetic models indicate higher doses are required to achieve the required CNS penetration which increases the risk of toxicity due to polysorbate 80. Discuss with Infectious Diseases.<sup>(6)</sup>
- 3 mg/kg loading dose with 1.5 mg/kg/dose once daily maintenance dose has been used.<sup>(7)</sup>

### Intravenous

#### Children (≥4 weeks):

**Loading dose:** 3 mg/kg (to a maximum of 200 mg) as a single dose on day one.<sup>(1, 3, 5, 7-9)</sup>

**Maintenance dose:** 1.5 mg/kg/dose (to a maximum of 100 mg) once daily.<sup>(1, 3, 5, 7-9)</sup>

**Dosing in Overweight and Obese Children:** Higher doses may be required in obese patients as there is increased clearance as a function of body weight.<sup>(7)</sup>

### Renal impairment:

- [eGFR calculator](#)
- No dosage adjustment is required in patients with renal impairment.<sup>(1, 6, 7, 9)</sup>

### Hepatic impairment:

- No dosage adjustment is required in patients with hepatic impairment.<sup>(1, 6, 7, 9)</sup>
- Increased hepatic enzymes may occur during anidulafungin therapy. Patients with worsening hepatic function may require cessation of anidulafungin.<sup>(5, 6)</sup>

**RECONSTITUTION & ADMINISTRATION****Reconstitution**

- Reconstitute each 100 mg vial with 30 mL of water for injections to make a final concentration of 3.33 mg/mL. (1, 2, 6, 7)
- The powder is slow to dissolve and may take up to 5 minutes to dissolve. The final solution must be prepared immediately and should be clear and colourless. Further dilution is required before administration. (1, 2)

**Administration**

- The IV solution should be diluted to a final concentration of 0.77 mg/mL and infused at a rate of 1.1 mg/minute (1.4 mL/minute) or slower. (1-3, 6, 7, 10)
- Recommended volumes for final administration (1, 2, 5, 6, 10)

Dose	Suggested Final volume	Minimum infusion time
50 mg	65 mL	45 minutes
100 mg	130 mL	90 minutes
200 mg	260 mL	180 minutes

**COMPATIBILITY (LIST IS NOT EXHAUSTIVE)****Compatible fluids:**

- Glucose 5%
- Sodium chloride 0.9% (1, 2)

**Compatible at Y-site:**

[Compatibilities of IV drugs](#) must be checked when two or more drugs are given concurrently.

**MONITORING**

- Hepatic function must be monitored regularly. Liver function tests should be checked at baseline and monitored throughout treatment. Some paediatric studies have shown a higher incidence altered liver function tests in comparison to adults. Patients with increasing hepatic enzymes should be evaluated for risk/ benefit of continuation of anidulafungin. Cessation of anidulafungin may be warranted. (1, 5-8)

**ADVERSE EFFECTS**

**Common:** nausea, vomiting, diarrhoea, dyspepsia, rash, fever, headache, hypokalaemia or hyperkalaemia, increased liver enzymes, hypertension or hypotension, peripheral oedema, , thrombocytopenia, insomnia, anaemia, neutropenia. (3, 7)

**Infrequent:** hypomagnesaemia (3)

**Rare:** anaphylaxis, injection site reactions, infusion related reactions (e.g. rash, urticaria, flushing, chills, fever, itch, bronchospasm, dyspnoea ) are more likely if anidulafungin is infused at a rate faster than 1.1mg/minute.<sup>(2, 3, 7)</sup>

## STORAGE

- Store the vial between 2 and 8°C, do not freeze.<sup>(1, 2, 6, 7)</sup>

## 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 **anidulafungin**. 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

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