MONOGRAPH

Anidulafungin 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: Restricted (red) antifungal

ChAMP approval is required prior to prescription.

- Anidulafungin is indicated in the treatment of invasive candidiasis including candidaemia.[3, 4]
- 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.[1, 3, 5-7]
- 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. [1, 3, 5-8]

PRECAUTIONS

- Clinically significant hepatic abnormalities can occur with treatment.[5]
- 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.[1, 5, 6]

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.[1, 5, 7]
- 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.[6]
- 3 mg/kg loading dose with 1.5 mg/kg/dose once daily maintenance dose has been used.[7]

Intravenous

Children (≥4 weeks):

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

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

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.[7]

Renal impairment:

- eGFR calculator
- No dosage adjustment is required in patients with renal impairment.[1, 6, 7, 9]

Hepatic impairment:

- No dosage adjustment is required in patients with hepatic impairment.[1, 6, 7, 9]
- Increased hepatic enzymes may occur during anidulafungin therapy. Patients with worsening hepatic function may require cessation of anidulafungin.[5, 6]

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 make 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.[2, 3, 7]

STORAGE

- Store the vial between 2 and 8°C, do not freeze.[1, 2, 6, 7]

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

1. AusDI [Internet]. Health Communication Network Pty Ltd. 2024 [cited 2024 October 29th].
2. Symons K. Wong Ee. Australian injectable drugs handbook. Abbotsford: The Society of Hospital Pharmacists of Australia; 2023.
3. Australian Medicines Handbook. Adelaide, S. Aust.: Australian Medicines Handbook; 2024 [cited 2024 3rd October]. Available from: https://amhonline-amh-net-au.pklibresources.health.wa.gov.au/.
4. Antibiotic Writing Group. Therapeutic Guidelines - Antibiotic. West Melbourne: Therapeutic Guidelines Ltd; 2022. Available from: https://tgldcdp-tg-org-au.pklibresources.health.wa.gov.au/etgAccess.
5. Clinical Pharmacology powered by ClinicalKey [Internet]. Elsvier. 2024 [cited 2024 October 29th]. Available from: https://www-clinicalkey-com.pklibresources.health.wa.gov.au/pharmacology/.
6. Electronic Medicines Compendium (emc). Surrey: DataPharm Ltd; 2024.
7. Up To Date - Paediatric Drug information [Internet]. Lexicomp. 2024 [cited 2024 October 29th]. Available from: https://www-uptodate-com.pklibresources.health.wa.gov.au/contents/table-of-contents/drug-information/pediatric-drug-information.
8. Royal Australian College of General Practitioners, Pharmaceutical Society of Australia, Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists. AMH: Children's Dosing Companion. Adelaide: Australian Medicines Handbook Pty Ltd; 2022.

9. IBM Micromedex [Internet]. Truven Health Analytics. 2023 [cited 2024 October 29th]. Available from: http://www-micromedexsolutions-com.pklibresources.health.wa.gov.au/micromedex2/librarian.
10. Miller J, editor. AHFS Drug Information. Maryland: American Society of Health-System Pharmacists; 2022.

This document can be made available in alternative formats on request.

File Path:	*W:\Safety & Quality\CAHS\CLOVERS MEDICAL Pharmacy\Procedures Protocols and Guidelines\ChAMP\Word\Monographs\PCH Templated (ED Guidelines)*		
Document Owner:	Head of Department – Infectious Diseases		
Reviewer / Team:	Children's Antimicrobial Management Program Pharmacist		
Date First Issued:	March 2019	Last Reviewed:	November 2024
Amendment Dates:	November 2021, November 2024	Next Review Date:	December 2027
Approved by:	Drugs and Therapeutics Committee	Date:	December 2024
Endorsed by:	Chair, Drugs and Therapeutics Committee	Date:	December 2024
Aboriginal Impact Statement and Declaration (ISD)		Date ISD approved:	31st August 2023
Standards Applicable:	NSQHS Standards: NSMHS: N/A Child Safe Standards: N/A		

Printed or personally saved electronic copies of this document are considered uncontrolled

Healthy kids, healthy communities
Compassion | Excellence | Collaboration | Accountability | Equity | Respect
Neonatology | Community Health | Mental Health | Perth Children's Hospital