



MONOGRAPH

Liposomal amphotericin B (AmBisome®) 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](#)

! HIGH RISK MEDICINE !

QUICKLINKS

Dosage/Dosage Adjustments	Administration	Compatibility	Monitoring
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DRUG CLASS

Polyene antifungal.^(1, 2)

Liposomal amphotericin B (AmBisome®) is a [High Risk Medicine](#).

INDICATIONS AND RESTRICTIONS

AmBisome® is indicated in the treatment of severe systemic or deep mycoses and suspected or proven infection in febrile neutropenic patients unresponsive to broad spectrum antibacterials.^(3, 4)

AmBisome® is also used for prophylaxis in patients at high risk of mould infections who are intolerant to micafungin prophylaxis.⁽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).
- 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.

Inhaled: Restricted (red) antifungal

ChAMP approval is required prior to prescription. – Refer to the [inhaled liposomal amphotericin B monograph](#).

CONTRAINDICATIONS

- Hypersensitivity to any formulation of amphotericin B or any component of the formulation.^(1, 4, 5)
- Liposomal amphotericin B (AmBisome®) is **INCOMPATIBLE** with sodium chloride 0.9% - IV lines should be flushed with glucose 5% prior to administration.^(1, 5, 6)

PRECAUTIONS

Different preparations of intravenous amphotericin are available and vary in their pharmacodynamics, pharmacokinetics, dosage and administration.

They are **NOT** considered interchangeable. To avoid confusion, they should be prescribed by trade name.^(2, 6, 7)

- Use with caution in patients with cardiac disease as liposomal amphotericin B may cause chest pain, tachycardia, hypotension or hypertension.⁽⁵⁾
- Each 50 mg vial of liposomal amphotericin B contains 900 mg of sucrose.^(1, 6)

FORMULATIONS

Listed below are products available at PCH. Other formulations may be available; check with pharmacy if required:

- Liposomal amphotericin B 50 mg powder for injection vial (AmBisome®)

Imprest location: [Formulary One](#)

DOSAGE & DOSAGE ADJUSTMENTS

Neonates: [Refer to Neonatal Medication Protocols](#)

IV - Children:

- **Treatment of Aspergillus infection (suspected or confirmed) including prolonged febrile neutropenia:** 3 mg/kg/dose given once daily.^(3-5, 7)
- **Treatment of Mucormycosis:** 5 mg/kg/dose given once daily. May be increased to a maximum of 10 mg/kg once daily in CNS disease only on advice from an infectious diseases or clinical microbiology consultant.^(3, 4, 7)
- **Mould prophylaxis:** 1 mg/kg/dose given either 3 times per week or once daily.⁽⁷⁾

Inhalation:

Please refer to separate [Inhaled liposomal amphotericin B monograph](#)

Dosing in Overweight and Obese Children:

- There is limited information regarding dosing of liposomal amphotericin B in obesity.
- Adult studies suggest dosing by adjusted body weight for patients requiring standard doses of 3 mg/kg/dose. For patients requiring 5 mg/kg/dose or higher or those that are critically ill, doses can be based on total body weight.⁽⁸⁾

Renal impairment:

- [eGFR calculator](#)
- No dose reduction is required in renal impairment, however renal function should be monitored as use may be associated with a further decline in renal function.^(3, 5)
- Care should be taken with the concomitant use of other nephrotoxic agents due to the increased risk of renal impairment.⁽³⁾

Hepatic impairment:

- No dosage reduction is required in hepatic impairment, however regular monitoring of hepatic function is recommended.⁽⁵⁾

RECONSTITUTION & ADMINISTRATION**Reconstitution:**

- Reconstitute each vial with 12 mL of water for injection to obtain a concentration of 4 mg/mL (assumes a 0.5 mL displacement volume for the powder).^(1, 5, 6, 9, 10)
- Shake the vial for 30 seconds to ensure the powder has dissolved.^(1, 5, 6, 10)
- Withdraw the required dose and using a 5 micrometre filter (supplied) add the solution to glucose 5% to produce a final concentration between 0.2 mg/mL and 2 mg/mL.

Administration:

- Flush the line before and after infusion with glucose 5%.^(5, 6)
- Infuse at a concentration of between 0.2 mg/L and 2 mg/L, given over 2 hours.^(4, 5)
- For doses less than 5 mg/kg/dose, if no adverse effects are seen, subsequent infusions may be administered over 1 hour.^(3, 6)

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

Glucose 5%⁽⁶⁾

Compatible at Y-site:

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

INCOMPATIBLE drugs:

- AmBisome® is **INCOMPATIBLE** with sodium chloride 0.9% - IV lines should be flushed with glucose 5% prior to and immediately following administration.^(1, 6)

MONITORING

- Renal function and electrolytes, (including magnesium, potassium and sodium) should be monitored three times a week throughout therapy and until stable after treatment is ceased.⁽³⁾
- Full blood picture, and hepatic function should be monitored twice weekly throughout therapy and until stable after treatment is ceased.⁽³⁾
- Patients should be monitored for infusion related reactions (especially during the first dose). Paracetamol and/or an antihistamine or a slowing of the infusion rate may be required.⁽³⁾

ADVERSE EFFECTS

Common: thrombophlebitis, anaemia, nephrotoxicity, hypoxia, hyperglycaemia, altered liver function tests, tachycardia and electrolyte abnormalities (hypokalaemia, hyponatraemia, hypomagnesaemia).^(3, 5)

Infusion related reactions are common and may include fever, chills, hypotension, anorexia, nausea, vomiting, headache, malaise, muscle and joint pain. They usually lessen with continued treatment and with a slowing of the infusion rate and the use of paracetamol and/or an antihistamine.⁽³⁾

Infrequent: hypotension, hypertension, arrhythmias, blood dyscrasias, Gastrointestinal (GI) bleeding, hepatotoxicity, rash, neurological effects, hypernatraemia.⁽³⁾

Rare: anaphylactoid reactions, hyperkalaemia, cardiac arrest, encephalopathy, deafness, tinnitus, vertigo, vision disorders.^(3, 10)

STORAGE

- 50 mg powder for injection vial should be stored below 25 °C^(1, 6)
- Products prepared by PCS should be stored between 2 and 8 °C.⁽⁶⁾

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 **liposomal amphotericin B (AmBisome®)**. 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. MIMS Australia. MIMS online [full product information]. St Leonards, N.S.W: CMP Medica Australia.; 2022 [cited 2022 6th Dec].
2. 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>.
3. Australian Medicines Handbook. Adelaide, S. Aust.: Australian Medicines Handbook; 2022 [cited 2022 6th Dec]. Available from: <https://amhonline-amh-net-au.pklibresources.health.wa.gov.au/>.
4. Up To Date - Paediatric Drug information [Internet]. Lexicomp. 2022 [cited 2023 Jan 19th]. Available from: <https://www-uptodate-com.pklibresources.health.wa.gov.au/contents/table-of-contents/drug-information/pediatric-drug-information>.
5. Clinical Pharmacology powered by ClinicalKey [Internet]. Elsevier. 2022 [cited 2023 Mar 13th]. Available from: <http://www.clinicalpharmacology-ip.com.pklibresources.health.wa.gov.au/default.aspx>.
6. Symons K. Ermer J. (editors). Australian injectable drugs handbook. Collingwood: The Society of Hospital Pharmacists of Australia; 2022.
7. 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.
8. Ting MH, Spec A, Micek ST, Ritchie DJ, Krekel T. Evaluation of Total Body Weight versus Adjusted Body Weight Liposomal Amphotericin B Dosing in Obese Patients. *Antimicrob Agents Chemother*. 2021;65(9):e0236620.
9. Plover C. Paediatric Injectable Guidelines. Flemington, Vic: The Royal Children's Hospital; 2020.
10. Paediatric Formulary Committee. BNF for Children: 2022. London: BMJ Group Pharmaceutical Press; 2022.

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Compassion

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Collaboration

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Neonatology | Community Health | Mental Health | Perth Children's Hospital