




MONOGRAPH	
<u>Inhaled</u> Liposomal Amphotericin B Monograph (AmBisome)-Paediatric	
Scope (Staff):	Clinical Staff – Medical, Nursing , Pharmacy
Scope (Area):	Perth Children's Hospital (PCH)
<p align="center">Child Safe Organisation Statement of Commitment</p> <p>The Child and Adolescent Health Service (CAHS) commits to being a child safe organisation by meeting the National Child Safe Principles and National Child Safe Standards. This is a commitment to a strong culture supported by robust policies and procedures to ensure the safety and wellbeing of children at CAHS.</p>	

This document should be read in conjunction with this [DISCLAIMER](#)

<p>DESCRIPTION</p> 	<ul style="list-style-type: none"> Liposomal amphotericin (AmBisome®) is a polyene antifungal⁽¹⁾, it binds irreversibly to ergosterol in the fungal cell membrane resulting in fungal cell death by altering the permeability and allowing leakage of the intracellular contents.^(2, 3) Inhaled liposomal amphotericin B (AmBisome®) is a High Risk Medicine. Refer to the Intravenous liposomal amphotericin monograph – paediatric for information on the use and administration of intravenous liposomal amphotericin B (AmBisome®)
<p>INDICATIONS AND RESTRICTIONS</p>	<p>Inhaled: Restricted (red) antifungal</p> <ul style="list-style-type: none"> ChAMP approval is required prior to prescribing Inhaled AmBisome® should only be initiated in conjunction with a Clinical Microbiologist or Infectious Diseases Consultant where there is clinical suspicion of <i>Aspergillus</i> lung infection or colonisation where the infection/colonisation is considered to be potentially harmful, such as in Cystic Fibrosis or Allergic Bronchopulmonary Aspergillosis (ABPA). Inhaled therapy may also be considered in <ul style="list-style-type: none"> Immunosuppressed patients at high risk of invasive fungal infection who are intolerant or unable to take other systemic antifungal prophylaxis⁽⁴⁾ Approval of inhaled AmBisome® for the treatment of ABPA will be considered only if all the following criteria have been met: <ol style="list-style-type: none"> 1) <i>Aspergillus</i> infection: <i>Aspergillus</i> has been isolated from a

	<p>respiratory specimen or precipitin/IgG to <i>A. fumigatus</i>.⁽⁵⁾</p> <p>2) Compatible signs/symptoms: Clinical deterioration (cough, wheeze, exercise intolerance, exercise induced asthma, decline in pulmonary function, increased sputum) not attributable to another aetiology OR new abnormalities chest imaging unresponsive to antibiotic therapy.</p> <p>3) Allergic sensitisation: Serum total IgE >500IU/ml OR positive skin prick test or IgE to <i>A. fumigatus</i>⁽⁵⁾</p> <p>4) Receiving steroids</p> <p>5) Failure to respond after a minimum of 8 weeks of itraconazole at therapeutic levels OR intolerance to itraconazole</p>
CONTRAINDICATIONS	<ul style="list-style-type: none"> Previous hypersensitivity to liposomal amphotericin B (AmBisome[®]) or any of its constituents.⁽¹⁾
PRECAUTIONS	<ul style="list-style-type: none"> Liposomal amphotericin B (AmBisome[®]) is marketed for intravenous administration the suggested dose and dilution in this monograph is very different and suitable for inhalation only.
FORMULATIONS	<p>Available at PCH:</p> <ul style="list-style-type: none"> 50mg powder for reconstitution (AmBisome[®]) <p>Other formulations available:</p> <ul style="list-style-type: none"> Nil
DOSAGE	<ul style="list-style-type: none"> 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. <p>Neonates (less than 30 days of age):</p> <ul style="list-style-type: none"> Not routinely used in neonates, contact an Infectious Diseases Physician or Clinical Microbiologist for advice. <p>Children:</p> <ul style="list-style-type: none"> 25mg inhaled via nebuliser THREE times a week (in the evening) for 2 months, then ONCE a week for 2 months or for as long as therapy/ prophylaxis is required.⁽⁶⁾
DOSAGE ADJUSTMENT	<p>No dosage adjustment is required in hepatic or renal impairment due to minimal systemic absorption.⁽³⁾</p>

RECONSTITUTION	<ul style="list-style-type: none"> • Reconstitute 50mg vial with 12mL of Water for Injections and shake well (for at least 30 seconds).^(1, 7) • Inpatient use: Discard any remaining solution in the vial. • Outpatient use: When used for inhalation, this may be stored for up to 7 days between 2 and 8°C if protected from light and may be used for the subsequent dose.^(6, 7)
ADMINISTRATION	<p>Inhalation:</p> <ul style="list-style-type: none"> • The nebuliser mask, tubing and bowl must be washed well with warm soapy water and then rinsed in warm water and dried with a clean, lint free cloth PRIOR to and AFTER administration to remove any traces of sodium chloride as AmBisome[®] is incompatible with sodium chloride. • Inhaled AmBisome[®] should be administered via a PARI nebuliser as per the PARI Nebuliser Administration guideline, ensuring that no sodium chloride is added to the nebuliser pot as AmBisome[®] is incompatible with sodium chloride.⁽⁷⁾ • Draw up 25mg (6mL) of the reconstituted solution with a 5 micron blunt filter needle, remove the filter needle from the syringe BEFORE placing the dose in the nebuliser pot. • Patients on hypertonic saline or any other nebulised product which may contain sodium chloride 0.9% should omit this on the evening when they have their nebulised AmBisome[®] as AmBisome[®] is not compatible with sodium chloride. • If this is not possible, patients should allow a minimum of one hour interval between the two different nebulised medicines and ensure that the nebuliser mask, tubing and bowl are washed well with warm soapy water and then rinsed in warm water and dried with a clean, lint free cloth between the two agents.
MONITORING	<ul style="list-style-type: none"> • The first dose of inhaled AmBisome[®] should be administered in the hospital or in outpatient clinic under supervision to ensure that the patient does not suffer from any significant adverse effects. • Some patients may require administration of a bronchodilator prior to (or after) use.⁽⁵⁾ If so, this should be always administered via a metered dose inhaler (MDI) and not a nebuliser which contains sodium chloride 0.9%.⁽⁸⁾
ADVERSE EFFECTS	<ul style="list-style-type: none"> • Negligible systemic absorption with no expected systemic side effects. • Common: cough, wheezing, mild difficulty breathing, shortness of breath, reduced oxygen saturation, nausea, vomiting, bad taste, dysphagia bronchospasm, decline in pulmonary function.^(8, 9)




COMPATIBLE FLUIDS	<ul style="list-style-type: none"> Glucose 5%⁽⁷⁾ AmBisome® is incompatible with sodium chloride solutions.^(1, 7)
STORAGE	<ul style="list-style-type: none"> Store vials below 25°C.⁽¹⁾ Inpatient use: Discard any remaining solution in the vial. Outpatient use: When reconstituted and used for inhalation, may be stored for up to 7 days between 2 and 8°C if protected from light. May be used for the subsequent dose.^(6, 7)
INTERACTIONS	<p>Inhaled liposomal amphotericin B (AmBisome®) 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.</p> <ul style="list-style-type: none"> Inhaled liposomal amphotericin B (AmBisome®) is incompatible with sodium chloride solutions.^(1, 7) Ensure the nebuliser mask, tubing and bowl is washed well with warm soapy water and rinsed with warm water prior to use.
COMMENTS	Each 50mg vial of liposomal amphotericin contains 900mg of sucrose ^(1, 2)
MANUFACTURER SAFETY DATA SHEET (SDS)	To access to 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 **inhaled liposomal amphotericin B**. Any variations to the doses recommended should be clarified with the prescriber prior to administration

Related internal policies, procedures and guidelines
PCH Antimicrobial Stewardship Policy
PARI Nebuliser Administration

References
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