



NEONATAL Medication Monograph

AMPHOTERICIN B (FUNGIZONE®)

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

Highly Restricted: Requires Microbiologist approval before commencing

SAS Category A (Item requires approval by TGA)

⚠ HIGH RISK Medication

Confusion may occur between the formulations of amphotericin

- Amphotericin B (Fungizone®)
- Liposomal Amphotericin B (Ambisome®)





Dosage, preparation and administration are different between forms and may lead to serious harm. Amphotericin B is nephrotoxic, patients should be monitored for renal function

Presentation	Vial: 50mg
Description	Polyene antifungal
Indications	Treatment of invasive fungal infections by susceptible fungi including <i>Candida spp.</i> , <i>Aspergillus spp.</i> and <i>Cryptococcus</i> species. Note: <i>Candida lusitanae</i> and <i>A. terreus</i> are resistant.
Contraindications	Hypersensitivity to amphotericin B
Precautions	Amphotericin B (conventional) has variable pharmacokinetics in neonates and this may lead to unexpected treatment failure or toxicity. Administer under close clinical supervision during the initial dosing. Anaphylaxis and respiratory distress have been reported in adults (though not in neonates). Renal impairment: Risk of nephrotoxicity. Concomitant use of corticosteroids and corticotropin (ACTH) should be avoided
Dosage	IV: 0.5–1 mg/kg/dose 24 hourly. Liaise with ID specialists for dose regimens for specific conditions

Adverse Reactions	<p>Common: Electrolyte derangements: Hypokalaemia, hypomagnesaemia, hyperkalaemia, hypocalcaemia. Thrombophlebitis at the injection site.</p> <p>Renal: Elevated urea and creatinine</p>
	<p>Serious: Nephrotoxicity</p> <p>Haematological: Anaemia, leucopenia, thrombocytopenia.</p> <p>Gastrointestinal: Diarrhoea, vomiting, elevated liver enzymes.</p> <p>Infusion-related reactions: Fever, hypotension (rare in neonates). Skin rashes.</p>
Interactions	<p>Increased risk of nephrotoxicity if used concurrently with other nephrotoxic drugs e.g. aminoglycosides, vancomycin. Monitor renal function and relevant drug concentrations closely.</p> <p>Amphotericin B may enhance the toxicity of flucytosine by increasing its cellular uptake and impeding its renal excretion.</p> <p>Corticosteroids and diuretics: May enhance the hypokalaemic effect of amphotericin B</p>
Compatible Fluids	<p>Fluids: Glucose 5%</p>
Preparation	<p><u>IV:</u> Available from CIVAS (KEMH & PCH)</p> <p><i>Amphotericin must be prepared in a Buffered Glucose solution</i></p> <p><u>Step 1</u></p> <p><i>Prepare buffered glucose solution.</i></p> <p>Add 0.6mL of a Buffer (<i>Potassium Dihydrogen Phosphate and Dipotassium Hydrogen Phosphate Concentrated Injection</i>) to a Glucose 5% 100mL bag.</p> <p>Withdraw and discard 10mL from the prepared glucose bag (to account for overfill volume)</p> <p><u>Step 2</u></p> <p><i>Preparation of Amphotericin</i></p> <p>Add 10mL Water for Injections to a 50mg vial of Amphotericin B</p> <p>Concentration is 50mg/10mL = 5mg/mL</p> <p>Shake vial until solution is clear</p> <p><u>Step 3</u></p> <p><i>Addition of Amphotericin to Buffered Glucose</i></p> <p>Add 2mL (10mg) of the reconstituted amphotericin vial to glucose bag</p> <p>Concentration is 10mg/100mL</p> <p>Final concentration = 0.1mg/mL of amphotericin B in Buffered Glucose 5%</p>

Administration	<p>IV infusion: Infuse over 2-6 hours.</p> <p>Flush the line before and after infusion with Buffered Glucose 5% (if available from pharmacy) or Glucose 5%</p> <p>Do not use sodium chloride – causes precipitation</p>
Monitoring	<p>Urine output.</p> <p>Full blood count (FBC) for anaemia and thrombocytopenia.</p> <p>Renal function (for elevated creatinine), electrolytes (for hypokalaemia) and liver function (for derangements of liver enzymes).</p> <p>Monitor serum concentrations of concomitant nephrotoxic drugs.</p>
Storage	<p>Vial: Store at 2–8°C. Protect from light.</p> <p>Reconstituted solution: Stable for 24 hours below 25°C.</p> <p>Do not use the reconstituted solution or infusion if cloudy or a precipitate is present.</p> <p>Protect unopened vial from light.</p> <p>There is no need to protect from light during the infusion.</p>
Notes	<p>Although amphotericin B formulations are known to cause nephrotoxicity and may cause hepatotoxicity, reducing the dose in these disease states is not currently recommended. If nephrotoxicity or hepatotoxicity is a significant concern, consider other antifungals.</p> <p>Do not filter</p> <p>Do not use the reconstituted solution or infusion if cloudy or a precipitate is present</p> <p>Discard vial immediately after use</p>
References	<p>Truven Health Analytics. Amphotericin B. In: NeoFax [Internet]. Greenwood Village (CO): Truven Health Analytics; 2019 [cited 2020 Jan 17]. Available from: https://neofax.micromedexsolutions.com/</p> <p>Society of Hospital Pharmacists of Australia. Amphotericin B. In: Australian Injectable Drugs Handbook [Internet]. [St Leonards, New South Wales]: Health Communication Network; 2019 [cited 2020 Jan 17]. Available from: http://aidh.hcn.com.au</p> <p>Australian Medicines Handbook. Title of monograph Amphotericin B In: Australian Medicines Handbook [Internet]. Adelaide (South Australia): Australian Medicines Handbook; 2019 [cited 2019 Nov 28]. Available from: https://amhonline.amh.net.au/</p>

Related clinical guidelines	Candida Infections High Risk Medicines List
Related policies	WNHS Policy: Antimicrobial Stewardship

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