University Hospitals of Derby and Burton NHS Foundation Trust

NICU: Amphotericin B Liposomal (Ambisome®) RDH Only

Reference No: MONO-PAEDS/562

Presentation:	Amphotericin Liposomal (Ambisome) 50 mg Injection
Indication:	Severe systemic or deep mycoses where toxicity (particularly nephrotoxicity) precludes use of conventional amphotericin. Suspected or proven infection in febrile neutropenic patients unresponsive to broad-spectrum antibacterials.
Dose:	**Prescribe generic name and proprietary name** **Neonate:** 1 mg/kg once daily (may be increased if necessary by 1 mg/kg each day up to 3 mg/kg once daily. Maximum dose 5 mg/kg once daily). NB: A first test dose* is recommended by *some* texts but not the BNF-C. The Neonatal Formulary 8th edition notes that anaphylaxis is rarely seen in the neonate and therefore a test dose is not usually required. NB: Ambisome is not licensed for use in children under 1 month
Route of administration:	Intravenous infusion over 30 to 60 minutes using infusion pump
Instructions for preparation and administration:	**First dose to be prepared by NICU, subsequent doses prepared by RDH pharmacy aseptic unit** 1. Reconstitute each 50mg vial with 12mL water for injections to give 4mg/mL. The manufacturer has added an overage in the 50mg vial to take into account displacement. 2. Shake vial vigorously for 30 seconds to disperse the powder, continue shaking until all powder has dispersed. The concentrate is a translucent, yellow dispersion. 3. Withdraw 2.5mL using the 5micron filter provided by the manufacturer in to a 5 ml syringe 4. Transfer this 2.5 mL into a syringe and make up to 20mL with Glucose 5%. This provides a 0.5mg/mL solution 5. Withdraw the required dose from the 0.5mg/mL solution ***If giving a test dose**: 100 micrograms/kg (max 1 mg) over 10 minutes. Use the patients prepared dose. Observe patient for any signs of adverse reaction/anaphylaxis for at least 30 minutes. If no severe allergic or anaphylactic reaction infuse remainder of dose over 30 to 60 minutes. If a non-anaphylactic infusion-related reaction occurs, infuse over 2 hours Line must be flushed with glucose 5% as amphotericin is **incompatible with sodium chloride 0.9%**. ** AVAILABLE IN 'ANTIBIOTICS' FOLDER ON SMART PUMP **
Prescribing	Prescribe test and subsequent doses on paper drug chart. **Important safety information MHRA/CHM advice**: risk of potentially fatal adverse reaction if formulations confused: fatal overdoses have been caused by errors where Fungizone® (non-lipid-based formulation of amphotericin B) was administered instead of lipid-based formulation. When prescribing and dispensing, **both complete generic name and proprietary name should be used**; product name and dose should be verified before administration, especially if dose prescribed exceeds maximum recommended dose for Fungizone®.

Known compatibility issues	Compatible: Glucose 5%, 10% Incompatible: Sodium chloride must **not** be used as a flush, **always** use glucose 5%. **No other drugs should be administered via same line as amphotericin B (Ambisome) whilst infusion is running.**
Additional Comments:	Avoid rapid infusion (risk of arrhythmias); toxicity is common (close supervision necessary). **Monitoring:** • Administration site – thrombophlebitis and irritation may occur • Regular laboratory evaluation of serum electrolytes, particularly potassium, magnesium and phosphate as well as renal, hepatic and hematopoietic function should be performed, at least once weekly during long-term treatment **Storage: Syringes/bags must be stored in the fridge and protected from light.** Light protective giving sets do **not** need to be used. Syringe/bag does **not** need to be protected from light when in use provided used within 24 hours.

Note: The contents of this monograph should be read in conjunction with information available in the BNFC and Medusa

References:

BNFc Amphotericin B, accessed via: https://bnfc.nice.org.uk/drugs/amphotericin-b/#indications-and-dose on 29/11/23

Medusa AmBisome, accessed via: https://www.medusaimg.nhs.uk/IVGuideDisplayMain.asp on 29/11/23

SPC AmBisome Liposomal 50mg Powder for dispersion for infusion, accessed via: AmBisome Liposomal 50 mg Powder for dispersion for infusion - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) on 13/10/23AmBisome Liposomal 50 mg Powder for dispersion for infusion - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) on 13/10/23

QPulse NICU Neonatal AmBisome worksheet NICU only, accessed via: http://app4/qpulse/default.aspx#ViewID=Revision_DetailView_Active&ObjectKey=1879&ObjectClassName=Bacchus.Xpo.BusinessObjects.Documents.Revision&mode=View on 29/11/23

Document control sheet

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AREA IN WHICH THIS MONOGRAPH APPLIES	NICU

DIVISIONAL AUTHORISATION	
GROUP	**DATE**
Paediatric monograph review group	22/12/23

AUTHORS		
Author	Position	Date
Updated by: Harriet Hughes	Advanced Pharmacist, Women's & Children's	November 2019
Checked by: Katie Kemble	Rotational Pharmacist	November 2019

If review:

	Position	Date
Transferred to new template by:	Amanpreet Bria, Shift Working Clinical Pharmacist Joanna Hurcombe Ellie Cheale Lamia Ahmed	November 2023 November 2023 December 2023

Change history:

Changes Reference	Change details	Date
1	Paediatric information separated from neonatal	June 2019
2	Allergy information when giving a test dose: - If no severe allergic or anaphylactic reaction infuse remainder of dose over 30-60 minutes.	November 2023
3	Reconstitution, dilution and administration information added as NICU will be making first dose out of hours. Subsequent doses will be picked up by aseptic unit.	November 2023