South Australian Neonatal Medication Guidelines

amphotericin (liposomal)

50mg injection

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Note:
This guideline provides advice of a general nature. This statewide guideline has been prepared to promote and facilitate standardisation and consistency of practice, using a multidisciplinary approach. The guideline is based on a review of published evidence and expert opinion.

Information in this statewide guideline is current at the time of publication.

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Health practitioners in the South Australian public health sector are expected to review specific details of each patient and professionally assess the applicability of the relevant guideline to that clinical situation.

If for good clinical reasons, a decision is made to depart from the guideline, the responsible clinician must document in the patient’s medical record, the decision made, by whom, and detailed reasons for the departure from the guideline.

This statewide guideline does not address all the elements of clinical practice and assumes that the individual clinicians are responsible for discussing care with consumers in an environment that is culturally appropriate and which enables respectful confidential discussion. This includes:

• The use of interpreter services where necessary,
• Advising consumers of their choice and ensuring informed consent is obtained,
• Providing care within scope of practice, meeting all legislative requirements and maintaining standards of professional conduct, and
• Documenting all care in accordance with mandatory and local requirements

This is a High Risk Medication

Potentially toxic medication. Overdose could be fatal.

Dose and Indications

Treatment of severe systemic fungal infections

Intravenous Infusion

2mg/kg every 24 hours

Doses up to 5mg/kg have been used in neonates with severe infection
Preparation and Administration

Intravenous Infusion

There are **TWO STEPS** to this process.

**STEP ONE:** Add 12mL of water for injection to 50mg amphotericin (liposomal) vial. Shake vigorously for 30 seconds to completely disperse the drug. The resulting solution contains 4mg/mL amphotericin (liposomal).

**STEP TWO:** Dilute 2mL of filtered amphotericin (liposomal) 4mg/mL with 14mL of 5% glucose (total of 16mL). The resulting solution contains 0.5mg/mL amphotericin (liposomal).

The 5 micron filter (supplied by manufacturer) should be used to add the amphotericin solution to the glucose.

Amphotericin (liposomal) is usually reconstituted and repacked by the sterile pharmacy department.

<table>
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<tr>
<th>Dose</th>
<th>1mg</th>
<th>2mg</th>
<th>3mg</th>
<th>4mg</th>
<th>5mg</th>
<th>6mg</th>
<th>7mg</th>
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</thead>
<tbody>
<tr>
<td>Volume</td>
<td>2mL</td>
<td>4mL</td>
<td>6mL</td>
<td>8mL</td>
<td>10mL</td>
<td>12mL</td>
<td>14mL</td>
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Infuse intravenously for the first time over **TWO** hours; subsequent infusions may be given over 1 hour if no adverse effects seen.

If an in-line membrane filter is used for the intravenous infusion, the mean pore size should not be less than 1 micron in diameter.

Flush IV lines with glucose 5% before and after the infusion. If this is not possible use a separate line.

Compatible Fluids

Glucose 5%, glucose 10% only

Adverse Effects

Common

Infusion reactions, thrombophlebitis, anaemia, nephrotoxicity, hypoxia, increased serum bilirubin, increased ALP, hyperglycaemia, tachycardia, hyponatremia.

Nephrotoxicity: Increased serum creatinine, hypokalaemia and hypomagnesaemia are frequent; anuria or oliguria may occur. However most of this information comes from the use of conventional amphotericin which is now discontinued.

Infusion reactions include fever, hypotension, vomiting, and pain; usually lessen with continued treatment.

Infrequent

Hypotension, hypertension, arrhythmias, blood dyscrasias, gastrointestinal bleeding, hepatotoxicity, rash, neurologic effects (e.g. seizure, hearing loss) hypernatremia.

Rare

Anaphylactoid reactions, hyperkalaemia (especially in renal impairment)
Monitor:
- At start of therapy: renal function
- At least three times a week: renal function, electrolytes (particularly potassium and magnesium)
- Twice a week during treatment and after treatment stops until stable: complete blood picture and hepatic function

Practice Points:
- Infectious Disease consultation is usually required prior to commencing therapy refer to local anti-microbial policy
- It is important that amphotericin (liposomal) does not come into contact with any product other than 5% or 10% glucose. For this reason, the line will need to be flushed with 5% glucose
- Ensure adequate hydration
- Do not infuse through an in-line filter
- Concomitant aminoglycosides will increase the risk of nephrotoxicity
- Concomitant diuretics & corticosteroids may cause excessive loss of serum potassium.
- It is not necessary to protect from light if used within 24 hours

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<td>SA Health Safety and Quality Strategic Governance Committee</td>
<td>Review date extended to 5 years following risk assessment. New template.</td>
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