South Australian Neonatal Medication Guidelines

Amiodarone
150mg/3mL injection, 5mg/ml suspension (WCH) *

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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 !
Amiodarone has serious adverse effects including the potential to worsen arrhythmia; these are slow to resolve after it is stopped due to very long half-life

Dose and Indications

Consult Cardiology prior to use

Supraventricular and ventricular arrhythmias

Intravenous infusion

Loading dose

5milligram/kg over 30 minutes

Maintenance dose

7-15 microgram/kg/minute

Oral

Loading dose

5-10milligram/kg/dose every 12 hours for 7 to 10 days

Maintenance dose

5-10milligram/kg/daily
Preparation and Administration

**Oral**

The *5mg/mL amiodarone solution is not commercially available however is manufactured at Women’s & Children’s Health Network Pharmacy.

Do not give the injection solution orally as it is an irritant.

**Intravenous**

Administer via a central line whenever possible. Amiodarone is an irritant; infusion via peripheral veins has been associated with pain and inflammation. Extravasation may cause necrosis or sloughing. Ensure line is patent before administration.

Discard if cloudiness or precipitate is present.

An in-line filter is recommended.

**Intravenous bolus**

Dilute 0.4mL of 50mg/mL amiodarone solution with 9.6mL of glucose 5% (to a total volume of 10mL). The resulting solution contains 2mg/mL amiodarone.

Administer bolus dose over 30 minutes.

<table>
<thead>
<tr>
<th>Dose</th>
<th>4mg</th>
<th>6mg</th>
<th>8mg</th>
<th>10mg</th>
<th>12mg</th>
<th>14mg</th>
<th>16mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>2mL</td>
<td>3mL</td>
<td>4mL</td>
<td>5mL</td>
<td>6mL</td>
<td>7mL</td>
<td>8mL</td>
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Note: In fluid restricted patients a maximum concentration of 6mg/mL may be used if administered via a central line.

**Continuous intravenous infusion**

Dilute 2mL of 50mg/mL amiodarone solution with 48mL of glucose 5% (to a total volume of 50mL). The resulting solution contains 2000microgram/mL (2mg/mL) amiodarone.

Diluted solution is stable for 12 hours. Protect from light.

<table>
<thead>
<tr>
<th>Formulae</th>
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</table>
| To calculate infusion rate (mL/hr):
| Rate (mL/hr) = 60 x dose (microgram/kg/min) x weight(kg) / Strength (microgram/mL) |
| To calculate the dose (microgram/kg/minute):
| Dose (microgram/kg/min) = Rate (mL/hr) x Strength (microgram/mL) / 60 x Weight (kg) |

Note: In fluid restricted patients a maximum concentration of 6000microgram/mL (6mg/mL) may be used if administered via a central line.
Compatible Fluids
Glucose 5%

Adverse Effects
Many of the adverse effects are related to dose and duration of treatment and may not appear for weeks, months or even years

Common
Transient elevation of hepatic aminotransferases, thyroid dysfunction, fever, skin pigmentation (blue-grey), corneal microdeposits, neurotoxicity (tremor, ataxia, paraesthesia, peripheral neuropathy, limb weakness), pulmonary toxicity, bradycardia, hypotension (IV)

Infrequent
Atrioventricular block, arrhythmias (new or exacerbated)

Rare
Hepatotoxicity, optic neuropathy, bronchospasm, alveolar haemorrhage, heart failure, acute respiratory distress, heart failure, torsades de pointes, thrombocytopenia, allergic rash, SIADH

Monitoring
> ECG, blood pressure and potassium levels; baseline and during IV infusion
> Baseline thyroid function test and liver function test, then repeat after 2 to 3 weeks and 6 monthly thereafter
> Baseline chest x-ray, then annually

Practice Points
> There are 2 types of pulmonary toxicity: acute inflammatory disorder, which can develop early or late – reversible if withdrawn early and may respond to corticosteroids; and chronic fibrotic form associated with prolonged exposure which is less reversible. If dyspnoea or non-productive cough perform chest x-ray as soon as possible.
> Amiodarone contains iodine and affects thyroxine metabolism; risk of thyroid dysfunction can persist up to a year after stopping treatment.
> Reversible benign corneal microdeposits occur in most patients but rarely affect vision (photophobia, visual haloes may occur).
> **Amiodarone can potentially interact with many drugs in some cases leading to toxic drug reactions.** Amiodarone has a very long half-life and may take weeks to months before a drug interaction fully develop; interactions may continue to occur for weeks to months after stopping.
  - Amiodarone increases digoxin concentration – reduce the digoxin dose to half maintenance. If loading digoxin, use full digoxin loading dose and half maintenance dose; monitor digoxin levels
- Avoid combination with drugs that may induce torsades de pointes arrhythmias, (i.e. sotalol)
- Amiodarone slows cardiac conduction, decreasing heart rate; avoid combination with drugs that have this effect (i.e. beta-blockers, calcium channel blockers as it can result in significant bradyarrhythmia)
- Electrolyte abnormalities (e.g. hypokalaemia) increase the risk of arrhythmias and may prolong the QT interval. Correct electrolyte abnormalities

Document Ownership & History

Developed by: SA Maternal, Neonatal & Gynaecology Community of Practice
Contact: Health.NeoMed@sa.gov.au
Endorsed by: Commissioning and Performance, SA Health
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<table>
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<tr>
<th>Approval Date</th>
<th>Version</th>
<th>Who approved New/Revised Version</th>
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<tr>
<td>17/09/20</td>
<td>V1</td>
<td>Lynne Cowan, Deputy CE, Commissioning and Performance, SA Department for Health and Wellbeing</td>
<td>Original Commissioning and Performance approved guideline.</td>
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Is this a new policy (V1)? Y
Does this policy amend or update an existing policy? N
If so, which version?
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If so, which policy (title)?

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