South Australian Neonatal Medication Guidelines

TrimETHOPRIM-sulfamethoxazole
80mg-400mg/5mL injection
40mg-200mg/5mL oral mixture

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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

Synonyms
Co-trimoxazole, trimethoprim compound

Dose and Indications
Dose according to trimethoprim content

Use is not recommended during the first 4 weeks of life due to the risk of kernicterus, except in the treatment of severe infections.

Infection due to susceptible organisms

<table>
<thead>
<tr>
<th>Intravenous, Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Postnatal Age (days)</strong></td>
</tr>
<tr>
<td>≤ 7 days</td>
</tr>
<tr>
<td>&gt; 7 days</td>
</tr>
</tbody>
</table>

Prophylaxis for urinary tract infection
Dose according to trimethoprim content

**Oral**
2mg/kg once a day
Preparation and Administration

**Intravenous**

Dilute 1mL (trimethoprim 16mg-sulfamethoxazole 80mg) of the 80mg-400mg/5mL injection with 24mL **sodium chloride 0.9%** (total volume 25mL).

The resulting solution contains 0.64mg/mL trimethoprim

Doses refer to trimethoprim component:

<table>
<thead>
<tr>
<th>Dose</th>
<th>4mg</th>
<th>6mg</th>
<th>8mg</th>
<th>10mg</th>
<th>12mg</th>
<th>16mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>6.3mL</td>
<td>9.4mL</td>
<td>12.5mL</td>
<td>15.6mL</td>
<td>18.8mL</td>
<td>25mL</td>
</tr>
</tbody>
</table>

Start the infusion within 30 minutes of dilution. Infuse over 60 to 90 minutes.

Discard if visible turbidity or crystallisation appears in the intravenous solution during the preparation or infusion.

**Intravenous – fluid restricted**

If neonate is fluid restricted, dilute 1mL (trimethoprim 16mg-sulfamethoxazole 80mg) of the 80mg-400mg/5mL injection with 15mL **glucose 5%** (total volume 16mL).

The resulting solution contains 1mg/mL trimethoprim

Doses refer to trimethoprim component:

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<thead>
<tr>
<th>Dose</th>
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<th>16mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>4mL</td>
<td>6mL</td>
<td>8mL</td>
<td>10mL</td>
<td>12mL</td>
<td>16mL</td>
</tr>
</tbody>
</table>

Prepare the solution immediately prior to infusion. Infuse over 60 minutes.

This intravenous solution is only stable for **one hour** as precipitation may occur in 1-2 hours.

Discard if visible turbidity or crystallisation appears in the intravenous solution during the preparation or infusion.

**Oral**

Oral mixture 40mg-200mg/5mL contains trimethoprim 8mg-sulfamethoxazole 40mg/mL.

Doses refer to trimethoprim component:

<table>
<thead>
<tr>
<th>Dose</th>
<th>4mg</th>
<th>6mg</th>
<th>8mg</th>
<th>10mg</th>
<th>12mg</th>
<th>16mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>0.5mL</td>
<td>0.75mL</td>
<td>1mL</td>
<td>1.25mL</td>
<td>1.5mL</td>
<td>2mL</td>
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</table>

Give with feeds to minimise gastrointestinal irritation.

**Compatible Fluids**

Glucose 5%, glucose 10%, sodium chloride 0.9%, glucose/sodium chloride solutions
Adverse Effects

Use with caution due to risk of bilirubin displacement and kernicterus (refer to practice points for additional risk factors and contraindications).

Common
Fever, nausea, vomiting, diarrhoea, anorexia, rash, itch, thrombocytopenia (rarely significant)

Hyperkalaemia can occur with usual doses but is more likely to be clinically significant as dose increases. Average onset is 4–5 days. Risk factors are high dose and renal impairment.

Infrequent
Photosensitivity, blood dyscrasias (e.g. neutropenia)

Rare
Megaloblastic anaemia, methaemoglobinaemia, erythema, hypoglycaemia, hepatitis, crystalluria, urinary obstruction with anuria/oliguria, *Clostridium difficile*- associated disease, aseptic meningitis

Hypersensitivity may present with fever, cough, rash, eosinophilia; the most serious effects include anaphylaxis, Stevens-Johnson syndrome, toxic epidermal necrolysis, serum sickness-like syndrome, lupus-like syndrome, pneumonitis, hepatitis, interstitial nephritis, systemic vasculitis and pancytopenia.

Monitoring
> Where treatment is prolonged (e.g. greater than 7 days):
  > Monitor potassium, renal function and blood count

Practice Points
> Trimethoprim prescribed on its own (e.g. for urinary tract infections) is usually preferred to combined therapy with sulfamethoxazole because of the side effects associated with the sulphonamide component
> Where no other oral option available, short term use is acceptable pending sourcing of trimethoprim suspension or other oral suspension. See caution below.
> Contraindicated in glucose-6-phosphate dehydrogenase deficiency and bone marrow suppression
> Use with CAUTION in premature and newborn infants with:
  > jaundice as there is a risk of kernicterus (sulphonamides displace bilirubin from plasma albumin)
  > patients with severe haematological disorders (folic acid deficiency and blood dyscrasias may worsen). Contraindicated in megaloblastic anaemia due to folate deficiency
  > patients with renal impairment - reduced or less frequent dosage is recommended
  > patients with hepatic impairment
  > known hyperkalaemia and/or concomitant use of medications that increase the risk of hyperkalaemia
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Document Ownership & History

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If so, which policy (title)?

<table>
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<th>Version</th>
<th>Who approved New/Revised Version</th>
<th>Reason for Change</th>
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<td>29/06/2022</td>
<td>V3.0</td>
<td>Domain Custodian, Clinical Governance, Safety and Quality</td>
<td>Reviewed in line with 5 year review schedule</td>
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<td>31/8/2017</td>
<td>V2.0</td>
<td>SA Health Safety and Quality Strategic Governance Committee</td>
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