Clinical Guideline
azITHROMYCIN 500mg injection, 40mg/mL oral mixture

Policy developed by: SA Maternal, Neonatal & Gynaecology Community of Practice
Approved SA Health Safety & Quality Strategic Governance Committee on: 07 March 2017
Next review due: 31 March 2020

Summary
The azITHROMYCIN 500mg injection, 40mg/mL oral mixture Clinical Practice Guideline is for the administration of azITHROMYCIN to a neonate

Keywords
Azithromycin, chlamydia, pneumonia, conjunctivitis, vomiting, diarrhoea, candida infections, rash anaphylaxis, thrombocytopenia, pyloric stenosis, clinical guideline, azITHROMYCIN 500mg injection, 40mg/mL oral mixture, neonatal medication guideline

Policy history
Is this a new policy? N
Does this policy amend or update an existing policy? Y v1.0
Does this policy replace an existing policy? N
If so, which policies?

Applies to
All Health Networks
CALHN, SALHN, NALHN, CHSALHN, WCHN

Staff impact
All Staff

PDS reference
CG256

Version control and change history

<table>
<thead>
<tr>
<th>Version</th>
<th>Date from</th>
<th>Date to</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>November 2012</td>
<td>March 2017</td>
<td>Original version</td>
</tr>
<tr>
<td>2.0</td>
<td>07 March 2017</td>
<td>Current</td>
<td>Review, change to dosing</td>
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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

Dose and Indications

Treatment or prophylaxis of Bordetella pertussis infections

OR

Treatment of Chlamydia trachomatis pneumonia

Intravenous infusion / Oral

10mg/kg per dose once daily for 5 days

Intravenous administration should only be considered when oral therapy not suitable

Treatment of Chlamydia trachomatis conjunctivitis

Intravenous infusion / Oral

20mg/kg once daily for 3 days

Intravenous administration should only be considered when oral therapy not suitable
Preparation and Administration

**Intravenous**

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

<table>
<thead>
<tr>
<th>Dose</th>
<th>5mg</th>
<th>7.5mg</th>
<th>10mg</th>
<th>12.5mg</th>
<th>15mg</th>
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</thead>
<tbody>
<tr>
<td>Volume</td>
<td>2.5mL</td>
<td>3.75mL</td>
<td>5mL</td>
<td>6.25mL</td>
<td>7.5mL</td>
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</table>

Infuse over at least 60 minutes

**STEP ONE:** Add 4.8mL of water for injection to the azITHROMYCIN 500mg vial and shake gently to dissolve (total volume of 5mL). The resulting solution contains 100mg/mL azITHROMYCIN.

**STEP TWO:** Further dilute 0.2mL of the 100mg/mL azITHROMYCIN solution with 9.8mL of compatible fluid (total volume of 10mL). The resulting solution contains 2mg/mL azITHROMYCIN.

**Oral**

Refer to product information for reconstitution volume. The resulting solution after reconstitution contains 40mg/mL azITHROMYCIN.

<table>
<thead>
<tr>
<th>Dose</th>
<th>5mg</th>
<th>10mg</th>
<th>20mg</th>
<th>30mg</th>
<th>40mg</th>
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<tbody>
<tr>
<td>Volume</td>
<td>0.13mL</td>
<td>0.25mL</td>
<td>0.5mL</td>
<td>0.75mL</td>
<td>1mL</td>
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</table>

The reconstituted solution is stable for 10 days stored below 30°C.

**Compatible Fluids**

Glucose 5%, glucose/sodium chloride solutions, sodium chloride 0.45%, sodium chloride 0.9%

**Adverse Effects**

**Common**

Vomiting, diarrhoea, candidal infections, inflammation at the infusion site

**Infrequent**

Rash

**Rare**

Hypersensitivity (e.g. anaphylaxis, fixed drug eruptions, Stevens-Johnson syndrome, interstitial nephritis, ototoxicity), Clostridium difficile-associated disease, cholestatic hepatitis, pancreatitis, prolonged QT interval, blood dyscrasias (e.g. thrombocytopenia, pyloric stenosis [extremely rare])
Monitoring

Gastrointestinal tolerance

Practice Points

- Infusion of azITHROMYCIN with a concentration greater than 2mg/mL will result in a local infusion site reaction and should be avoided.
- While there is limited data for use in neonates, azITHROMYCIN is recommended for treatment and prophylaxis of pertussis.
- Prophylaxis with azITHROMYCIN is not recommended for neonates born to mothers with untreated Chlamydia.
- Approximately 50% of neonates with chlamydial conjunctivitis develop Chlamydia pneumonia.
- The mother of the infected neonates and her sexual contacts should be screened and/or treated for Chlamydia.