**MONOGRAPH**

**Phenoxyemethylpenicillin (penicillin V) Monograph - Paediatric**

<table>
<thead>
<tr>
<th>Scope (Staff):</th>
<th>Medical, Pharmacy, Nursing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope (Area):</td>
<td>All Clinical Areas</td>
</tr>
</tbody>
</table>

**Child Safe Organisation Statement of Commitment**

CAHS commits to being a child safe organisation by applying the National Principles for Child Safe Organisations. This is a commitment to a strong culture supported by robust policies and procedures to reduce the likelihood of harm to children and young people.

This document should be read in conjunction with this **DISCLAIMER**

**QUICKLINKS**

| Dosage/Dosage Adjustments | Administration | Compatibility | Monitoring |

**DRUG CLASS**

Penicillin antibiotic.\(^{(1)}\)

**INDICATIONS AND RESTRICTIONS**

- Phenoxyemethylpenicillin is indicated for **treatment** of dental infections (in combination with metronidazole), acute rheumatic fever (ARF) (if intolerant of intramuscular benzathine benzylpenicillin), and acute pharyngitis or tonsillitis due to *Streptococcus pyogenes* (in moderate / severe cases and or to prevent ARF) and Scarlet fever.\(^{(1-7)}\) Refer to The 2020 Australian guideline for prevention, diagnosis and management of ARF and RHD (3.2 edition).\(^{(8)}\)
- Phenoxyemethylpenicillin is indicated for **prophylaxis** against infection due to encapsulated organisms in susceptible hosts (e.g. asplenia, post haematopoietic stem cell transplantation) and as secondary prophylaxis for ARF (if intolerant to intramuscular benzathine benzylpenicillin).\(^{(1-3, 8)}\)

**Oral: Unrestricted (green) antibiotic**

This is not a restricted agent. Follow standard ChAMP guidelines where appropriate.
CONTRAINDICATIONS
- Hypersensitivity to phenoxymethylpenicillin, any component of the formulation or a history of high-risk allergy to other penicillins.\(^{(1,3-6)}\)

PRECAUTIONS
- Phenoxymethylpenicillin may be prescribed in selected patients with high-risk allergy to another Beta-lactam sub-class (e.g. some cephalosporins, carbapenems) in discussion with Immunology.\(^{(6)}\)
- In patients with a previous low risk reaction to phenoxymethylpenicillin or another penicillin (delayed rash [>1hr after initial exposure] without mucosal or systemic involvement) the risk of subsequent reaction is low. Re-challenge may be acceptable in discussion with Immunology.\(^{(3,4,6)}\)
- In patients with renal impairment, prolonged high doses may result in electrolyte disturbance or neurotoxicity (e.g. seizures, coma), and may increase risk of neutropenia.\(^{(1,4)}\)

FORMULATIONS
Listed below are products available at PCH, other formulations may be available, check with pharmacy if required:
- 250 mg tablets and capsules
- 50 mg/mL powder for suspension
Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Neonates: Refer to Neonatal Medication Protocols

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment of acute pharyngitis or tonsillitis due to \textit{S. pyogenes} (including scarlet fever)</td>
<td>\textbf{Child $\geq$ 4 weeks – 18 years:} 15 mg/kg/dose (to a maximum of 500 mg) 12 hourly for \textbf{10 days}.(^{(1,2,8,9)}) The full 10 day course is required to eradicate \textit{S. pyogenes} from the nasopharynx.(^{(1,2)})</td>
</tr>
<tr>
<td>Note: Antibiotics are not indicated for mild tonsillitis in children not at risk of ARF.(^{(1,9)})</td>
<td></td>
</tr>
</tbody>
</table>

| Treatment of ARF (if intolerant of intramuscular benzathine benzylpenicillin) | \textbf{Child $\geq$ 4 weeks – 18 years:} 15 mg/kg/dose (to a maximum of 500 mg) 12 hourly for \textbf{10 days}.\(^{(8,9)}\) |

| Dental infections (severe superficial infections) | \textbf{Child $\geq$ 4 weeks – 18 years:} 12.5 mg/kg/dose (to a maximum of 500 mg) four times a day for \textbf{5 days} in combination with metronidazole.\(^{(1,7)}\) |
### Prophylaxis

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secondary prophylaxis for ARF</td>
<td><strong>Child ≥ 4 weeks – 18 years</strong>: 250 mg/dose twice daily for 10 years.(^{(1, 8, 9)})</td>
</tr>
<tr>
<td>Note: IM Benzathine benzylpenicillin is preferred for treatment and prophylaxis of ARF/Rheumatic Heart Disease (RHD) due to improved efficacy and patient compliance.(^{(1, 8, 9)})</td>
<td></td>
</tr>
</tbody>
</table>
| Prophylaxis in asplenia, sickle cell anaemia, functional hyposplenia, post splenectomy or post Haematopoietic stem cell transplantation (HSCT) | **Child <1 year old**: 62.5 mg/dose twice daily.\(^{(2, 6)}\)  
**Child 1-< 5 years old**: 125 mg/dose twice daily.\(^{(2, 6)}\)  
**Children ≥ 5 old**: 250mg/dose twice daily.\(^{(2, 6)}\)  
Note: Amoxicillin is often preferred for this indication as it is administered once daily. Refer to ChAMP Medical Prophylaxis Guideline and Asplenia, Hyposplenia and Complement Deficiency Vaccination and Prophylaxis |

**Dosing in Overweight and Obese Children**: Dose based on measured body weight.\(^{(10)}\)

### Renal impairment:
- No dosage adjustment is required in renal impairment; however, the half-life may be prolonged in significant renal impairment.\(^{(3, 4)}\)
- The potassium content of the preparation should be considered in patients with severe renal impairment.\(^{(11)}\)

### Hepatic impairment:
- There are no specific recommendations for dosage adjustment in patients with hepatic impairment. It appears that no dose adjustment is necessary.\(^{(3, 4)}\)

### RECONSTITUTION & ADMINISTRATION
- May be given without regard to food, however absorption may be slightly higher if administered on an empty stomach.\(^{(3, 5)}\)

### Oral powder for suspension 50mg/mL
- Reconstitute as per the product information with water as follows: Tap bottle until all the powder flows freely, add the total volume of water for reconstitution and shake vigorously to suspend the powder. Store the reconstituted suspension in a refrigerator between 2°C and 8°C and discard any remaining suspension after 10 days.\(^{(11)}\)

### MONITORING
- Renal, hepatic and haematological function should be monitored with prolonged, high dose therapy (i.e. treatment doses for longer than 10 days).\(^{(1, 4)}\)
**ADVERSE EFFECTS**

**Common:** diarrhoea, nausea, immunological reactions (allergy, rash, erythema, urticaria, contact dermatitis, fever, angioedema, bronchospasm, interstitial nephritis, haemolytic anaemia, eosinophilia, serum sickness-like syndrome, exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis).\(^{(1, 6)}\)

**Infrequent:** vomiting, *Clostridoides difficile* associated disease.\(^{(1, 6)}\)

**Rare:** black tongue, electrolyte disturbances, neurotoxicity (with high dose e.g. drowsiness, hallucinations, coma, seizures), bleeding, blood dyscrasias (e.g. thrombocytopenia, neutropenia).\(^{(1, 6)}\)

**STORAGE**

50 mg/mL oral powder for suspension:
- Prior to reconstitution: Store below 25°C.\(^{(11)}\)
- After reconstitution: Refrigerate (between 2-8°C).\(^{(11)}\)
- Refer to packaging for storage conditions as this may differ between brands and strengths.

Tablets and capsules:
- Store below 25°C (refer to packaging for storage conditions as this may differ between brands and strengths).\(^{(11)}\)

**INTERACTIONS**

This medication may interact with other medications; consult PCH approved references (e.g. *Clinical Pharmacology*), a clinical pharmacist or PCH Medicines Information Service on extension 63546 for more information.

**Please note:** The information contained in this guideline is to assist with the preparation and administration of phenoxymethylpenicillin (*penicillin V*). Any variations to the doses recommended should be clarified with the prescriber prior to administration**

**Related CAHS internal policies, procedures and guidelines**

- Antimicrobial Stewardship Policy
- ChAMP Empiric Guidelines and Monographs
- KEMH Neonatal Medication Protocols
- ChAMP Medical Prophylaxis Guideline
- Asplenia, Hyposplenia and Complement Deficiency Vaccination and Prophylaxis
References
