Children's Antimicrobial Management Program (ChAMP)

MONOGRAPH

Phenoxymethylpenicillin (penicillin V) Monograph Paediatric

Scope (Staff):	Medical, Pharmacy, Nursing
Scope (Area):	All Clinical Areas

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					
<u>Dosage/Dosage</u> <u>Adjustments</u>	Administration	Compatibility	Monitoring		

DRUG CLASS

Penicillin antibiotic.(1)

INDICATIONS AND RESTRICTIONS

- Phenoxymethylpenicillin 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)
- Phenoxymethylpenicillin 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 <u>low risk reaction</u> 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

Treatment

Indication	Dose			
Treatment of acute pharyngitis or tonsillitis due to <i>S. pyogenes</i> (including scarlet fever)	Child ≥ 4 weeks – 18 years: 15 mg/kg/dose (to a maximum of 500 mg) 12 hourly for 10 days. (1, 2, 8, 9)			
	The full 10 day course is required to eradicate <i>S. pyogenes</i> from the nasopharynx. ^(1, 2)			
Note: Antibiotics are not indicated for mild tonsillitis in children not at risk of ARF. ^(1, 9)				
Treatment of ARF (if intolerant of intramuscular benzathine benzylpenicillin)	Child ≥ 4 weeks – 18 years: 15 mg/kg/dose (to a maximum of 500 mg) 12 hourly for 10 days. (8, 9)			
Dental infections (severe superficial infections)	Child ≥ 4 weeks – 18 years: 12.5 mg/kg/dose (to a maximum of 500 mg) four times a day for 5 days in combination with metronidazole. ^(1, 7)			

Prophylaxis

Indication	Dose
Secondary prophylaxis for ARF	Child ≥ 4 weeks – 18 years: 250 mg/dose twice daily for 10 years. (1, 8, 9)

Note: <u>IM Benzathine benzylpenicillin</u> is preferred for treatment and prophylaxis of ARF/Rheumatic Heart Disease (RHD) due to improved efficacy and patient compliance.^(1, 8, 9)

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, Clostridioides 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.

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

^{**}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**

References

- 1. Australian Medicines Handbook. Adelaide, S. Aust.: Australian Medicines Handbook; 2022 [cited 2023 2nd May]. Available from: https://amhonline-amh-net-au.pklibresources.health.wa.gov.au/.
- 2. Antibiotic Writing Group. Therapeutic Guidelines Antibiotic. West Melbourne: Therapeutic Guidelines Ltd; 2022. Available from: https://tgldcdp-tg-org-au.pklibresources.health.wa.gov.au/etgAccess.
- 3. Clinical Pharmacology powered by ClinicalKey [Internet]. Elsvier. 2022 [cited 2023 May 29th]. Available from: http://www.clinicalpharmacology-ip.com.pklibresources.health.wa.gov.au/default.aspx.
- 4. Up To Date Paediatric Drug information [Internet]. Lexicomp. 2022 [cited 2023 May 29th]. Available from: https://www-uptodate-com.pklibresources.health.wa.gov.au/contents/table-of-contents/drug-information/pediatric-drug-information.
- 5. IBM Micromedex [Internet]. Truven Health Analytics. 2022 [cited 2023 May 29th]. Available from: http://www-micromedexsolutions-com.pklibresources.health.wa.gov.au/micromedex2/librarian.
- 6. Paediatric Formulary Committee. BNF for Children: 2022. London: BMJ Group Pharmaceutical Press; 2022.
- 7. Therapeutic Guidelines Oral and Dental [Internet]. Therapeutic Guidelines. 2021.
- 8. RHDAustralia (ARF/RHD Writing Group). The Australian guideline for prevention, diagnosis and management of acute rheumatic fever and rheumatic heart disease (3.2 edition, March 2022): National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand; 2020.
- 9. Royal Australian College of General Practitioners, Pharmaceutical Society of Australia, Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists. AMH: Children's Dosing Companion. Adelaide: Australian Medicines Handbook Pty Ltd; 2022.
- 10. Kendrick JG, Carr RR, Ensom MH. Pediatric Obesity: Pharmacokinetics and Implications for Drug Dosing. Clin Ther. 2015;37(9):1897-923.
- 11. MIMS Australia. MIMS online [full product information]. St Leonards, N.S.W: CMP Medica Australia.; 2022 [cited 2023 21st Mar].

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Compassion

Excellence Collaboration Accountability

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