



MONOGRAPH

Primaquine 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

Dosage/Dosage Adjustments	Administration	Compatibility	Monitoring
---	--------------------------------	-------------------------------	----------------------------

DRUG CLASS

Antimalarial.⁽¹⁾

INDICATIONS AND RESTRICTIONS

- Primaquine is used to eradicate the intrahepatic forms (hypnozoites) of *Plasmodium vivax* and *Plasmodium ovale*. It is also used to eliminate the transmissible stage of *Plasmodium falciparum* in malaria receptive regions of Australia (just south of Broome, Tennant Creek to above Townsville – north of 19°S latitude).^(2, 3)
- Primaquine is also used as a second line agent in the treatment of *Pneumocystis jiroveci* pneumonia in combination with clindamycin, however this combination is associated with considerable toxicity.^(1, 3)

Oral: Monitored (orange) antiprotozoal

- If the use is consistent with a standard approved indication, this must be communicated to ChAMP by documenting that indication on all prescriptions (inpatient and outpatient).
- The ChAMP team will review if ongoing therapy is required and/or if the order does not meet [ChAMP Standard Indications](#).
- If use is not for a standard approved indication, phone approval must be obtained from ChAMP before prescribing.

CONTRAINDICATIONS

- Hypersensitivity to primaquine, 8-aminoquinolines or any component of the formulation.^(4, 5)
- Primaquine is contraindicated in patients with severe glucose-6-phosphate dehydrogenase (G6PD) deficiency.^(1, 4-7)
- Primaquine is contraindicated in acutely unwell patients who have a tendency to develop granulocytopenia (e.g. rheumatoid arthritis or systemic lupus erythematosus).^(1, 3, 4, 7, 8)
- Primaquine is contraindicated in patients currently receiving medications that may depress bone marrow or agents that may cause haemolytic anaemia due to the increased risk of myelosuppression.⁽⁴⁾
- Primaquine is contraindicated in pregnancy.⁽³⁻⁵⁾
- Primaquine must not be given concurrently with quinacrine, or to patients who have recently taken quinacrine due to the significant increased risk of toxicity.^(3, 4)

PRECAUTIONS

- Primaquine is associated with a definite risk of haemolysis in individuals with mild to moderate G6PD deficiency and should be avoided. In cases of mild to moderate G6PD deficiency a weekly dosage regimen may be tolerated. Discuss with the Infectious Diseases team.^(1, 3-6)
- Patients with nicotinamide adenine dinucleotide (NADH) methemoglobin reductase deficiency have reported methaemoglobinaemia with primaquine use.^(3, 4)
- Use primaquine with caution in patients with conditions that may increase the risk of QT prolongation.^(4, 5, 7)
- Primaquine should be avoided in children less than 6 months old due to the risk of methaemoglobinaemia.⁽¹⁾
- Discontinue primaquine promptly if signs of haemolytic anaemia occur (e.g. darkening urine, marked fall in haemoglobin).⁽⁵⁾
- 7.5 mg of primaquine base is equivalent to 13.2 mg of primaquine phosphate.^(1, 3)

FORMULATIONS

Listed below are products available at PCH, other formulations may be available, check with pharmacy if required:

- 7.5mg (primaquine base) oral tablet.

Imprest location: [Formulary One](#)

DOSAGE & DOSAGE ADJUSTMENTS

Children MUST be screened for G6PD deficiency before commencing therapy.^(1-4, 7, 8)
All doses are expressed as primaquine base.

Neonates and children less than 6 months of age:

- Not routinely used in neonates or infants less than 6 months of age due to the risk of methaemoglobinaemia. Contact Infectious Diseases consultants for advice.⁽¹⁾
- For children > 4 weeks of age doses of 0.5 mg/kg/dose once daily for 14 days have been given for radical cure / prevention of relapse.⁽⁴⁾

Oral:**Children ≥ 6 months of age:****Radical cure of *P. vivax* or *P. ovale* infection:**

- Should be used in conjunction a standard course of malaria therapy.^(1, 3, 9)

P. vivax

- **≥ 6 months of age and ≥ 70kg:** 30 mg once daily, until a total dose equalling 6 mg/kg is given.^(3, 6)
- **≥ 6 months of age and < 70kg:** 0.5 mg/kg/dose (to a maximum of 30 mg) once daily for 14 days. ^(3, 4, 9) 0.25 mg/kg/dose (to a maximum of 15 mg) can be given twice daily for 14 days in patients with nausea.⁽²⁾

***P. ovale*:**

- **≥ 6 months all weights:** 0.25 mg/kg/dose (to a maximum of 15 mg) once daily for 14 days.^(2, 4, 8)

Elimination of transmissible stage of *P. falciparum*:

- A single dose of primaquine should be given in addition to standard malaria therapy to eliminate the transmissible stage of *Plasmodium falciparum* in malaria receptive regions / low transmission areas of Australia just south of Broome, Tennant Creek to above Townsville – north of 19°S latitude).^(2, 3)
- This dose is best given with the initial treatment to ensure transmission is blocked as soon as possible.⁽⁶⁾
- 0.25 mg/kg as a single dose (to a maximum of 15 mg).^(3, 4, 9)

***Pneumocystis jiroveci* [carinii] pneumonia:** 0.25 mg/kg (to a maximum of 15 mg) once daily for 21 days in conjunction with oral clindamycin. This combination is associated with considerable toxicity and is not considered first line.⁽⁶⁾

Dosing in Overweight and Obese Children:

- There is limited information regarding the optimal dosing of malaria therapies in obese patients. Discuss dosing for obese or overweight children with the Infectious Diseases team.

Renal impairment:

- [eGFR calculator](#)
- No dosage adjustment appears to be necessary in renal impairment, however use with caution in patients with severe renal impairment.^(3, 4)

Hepatic impairment:

- As primaquine is metabolised by the liver, it should be used with caution in patients with hepatic impairment and liver function tests should be checked weekly.^(3, 4)

ADMINISTRATION

- Tablets should be given with food to mask the bitter taste and reduce gastrointestinal symptoms.^(3, 4, 6)
- When being used for the treatment of malaria, an additional dose should be given if the patient vomits within 1 hour of oral administration.⁽¹⁾

MONITORING

- G6PD deficiency **must** be excluded before commencing treatment courses. Exclusion of G6PD deficiency is not necessary for single doses.^(1, 3, 7, 8)
- Full blood count (FBC) should be conducted before commencing treatment and regularly with ongoing treatment.^(1, 3, 4)
- Visual colour check of urine should be conducted periodically during treatment as an indicator of haemolytic anaemia.^(3, 4)
- If primaquine is used in patients with cardiac disease or other QT prolonging drugs, ECG should be conducted.^(3, 7)

ADVERSE EFFECTS

Common: abdominal pain, dose related nausea and vomiting (generally less if taken with food), epigastric distress, dizziness, headache, leucocytosis.^(1, 4)

Infrequent: methaemoglobinaemia, haemolytic anaemia in G6PD deficiency.^(1, 8)

Rare: skin reactions, hypertension, arrhythmias, anaemia, leucopenia, granulocytopenia and agranulocytosis, cardiac arrhythmias, prolonged QT interval.^(1, 3, 4, 8)

STORAGE

Store tablets below 25°C.^(3, 5)

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 *primaquine*. 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](#)

[PCH Emergency Department Guidelines - Malaria](#)

References

1. Australian Medicines Handbook. Adelaide, S. Aust.: Australian Medicines Handbook; 2023 [cited 2023 30th October]. 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. Up To Date - Paediatric Drug information [Internet]. Lexicomp. 2023 [cited 2023 December 11th]. Available from: <https://www-uptodate-com.pklibresources.health.wa.gov.au/contents/table-of-contents/drug-information/pediatric-drug-information>.
4. Clinical Pharmacology powered by ClinicalKey [Internet]. Elsevier. 2023 [cited 2023 December 11th]. Available from: <https://www-clinicalkey-com.pklibresources.health.wa.gov.au/pharmacology/>.
5. MIMS Australia. MIMS online [full product information]. St Leonards, N.S.W: CMP Medica Australia.; 2023 [cited 2023 31th October].
6. 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.
7. IBM Micromedex [Internet]. Truven Health Analytics. 2023 [cited 2023 December 11th]. Available from: <http://www-micromedexsolutions-com.pklibresources.health.wa.gov.au/micromedex2/librarian>.
8. Paediatric Formulary Committee. BNF for Children: 2023. London: BMJ Group Pharmaceutical Press; 2023.
9. WHO guidelines for malaria, 16 October 2023. Geneva: World Health Organization; 2023 (WHO/UCN/GMP/2023.01 Rev.1). License: CC BY-NC-SA 3.0 IGO. .

This document can be made available in alternative formats on request.

File Path:	W:\Safety & Quality\CAHS\CLOVERS MEDICAL Pharmacy\Procedures Protocols and Guidelines\ChAMP\Word		
Document Owner:	Head of Department – Infectious Diseases		
Reviewer / Team:	Children’s Antimicrobial Management Program Pharmacist		
Date First Issued:	October 2013	Last Reviewed:	December 2023
Amendment Dates:	December 2017, November 2020, December 2023	Next Review Date:	January 2027
Approved by:	Drug and Therapeutics Committee	Date:	January 2024
Endorsed by:	Chair, Drug and Therapeutics Committee	Date:	January 2024
Aboriginal Impact Statement and Declaration (ISD)		Date ISD approved:	31/08/2023
Standards Applicable:	NSQHS Standards:    NSMHS: N/A Child Safe Standards: N/A		
Printed or personally saved electronic copies of this document are considered uncontrolled			
<div><div>Healthy kids, healthy communities</div><div>CompassionExcellenceCollaborationAccountabilityEquityRespect</div><div>Neonatology Community Health Mental Health Perth Children’s Hospital</div></div>			