MONOGRAPH

Artesunate 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

Artemesinin derivative antimalarial.[1, 2]

INDICATIONS AND RESTRICTIONS

Special access scheme product. SAS application(s) must be completed in accordance with the TGA regulations.

IV: Protected (red) antiprotozoal

ChAMP approval is required prior to prescription.

Artesunate is indicated for the treatment of severe malaria.[3, 4]

Refer to Emergency Department – Malaria guideline for further information.

CONTRAINDICATIONS

Hypersensitivity to artesunate, artemisinins or any component of the formulation.[5, 6]

PRECAUTIONS

- Resistance to artesunate has been documented in some areas of the Greater Mekong Subregion (including Thailand, Vietnam, Cambodia, Laos and Myanmar). Alteration to ongoing therapy may be required. Discuss with infectious diseases.[3]
- Artesunate does not have activity against *P. vivax* or *P. ovale* hypnozoites. Patients co-infected with these species will also require eradication therapy using primaquine.[3, 6]
- Malaria in pregnancy is a medical emergency, administer artesunate without delay.[4-6]
- Once reconstituted, artesunate solution contains 1.34 mg/mL of sodium.[7]
- Post artemisinin delayed haemolysis may occur, patients should be monitored for 4 weeks following completion of therapy. Patients with a higher parasite density may have a higher likelihood of haemolysis.[6] See Monitoring below.

FORMULATIONS

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

- 60 mg powder for injection vial plus 1 mL ampoule of sodium bicarbonate 5% as diluent.

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Neonates (< 4 weeks of age):

- Not routinely used in neonates, contact infectious disease or clinical microbiology consultants for advice.
- IV or IM doses of 3 mg/kg/dose at 0, 12 and 24 hours.[8]
- This dose should then be continued once daily for up to an additional 6 days. Ongoing oral therapy is required once oral absorption can be guaranteed. – discuss options with the infectious diseases team.[8]

Children ≥ 4 weeks

- **Weight < 20 kg:** 3 mg/kg/dose at 0, 12 and 24 hours. [3, 4, 6, 8]
- **Weight ≥ 20 kg:** 2.4 mg/kg/dose at 0, 12 and 24 hours. [3, 4, 6, 8]
- Artesunate should then be continued once daily until oral absorption can be guaranteed AND parasitemia is ≤1% for up to an additional 6 days.[3, 6]
- A full course of oral therapy (with artemether + lumefantrine) should be given for all patients after the completion of artesunate therapy.[3]
- Adjunctive therapy with ceftriaxone and paracetamol is recommended in all patients[3]. Refer to Emergency Department – Malaria guideline for further information.

Dosing in Overweight and Obese Children: There is minimal information available, dose based on actual body weight to avoid underdosing.[4]

Renal impairment:

- No dose change required for renal impairment.[5, 6]

Hepatic impairment:

- No dose change required for hepatic impairment. [5, 6]

RECONSTITUTION & ADMINISTRATION

Reconstitution (Dunate®, Artesun® and Malacef 60® brands):

- Reconstitute the artesunate 60 mg vial with 1 mL of the supplied sodium bicarbonate 5% diluent and shake gently for 2 to 3 minutes until dissolved. This should be further diluted with compatible fluid prior to administration. Once reconstituted, the solution should be used immediately.[5, 7]
- The powder is difficult to dissolve and care should be taken to ensure complete dissolution. The solution may be cloudy at first but will clear after a few minutes. The solution should be discarded if a precipitant is present or if the solution remains cloudy.[7, 9]
- The vial may require venting to relieve pressure after reconstitution.[7]
- Alternative brands may be available and have differing reconstitution information. Refer to product information.

Administration - IV injection:

- Further dilute the reconstituted solution with 5mL of sodium chloride 0.9 % to achieve a final concentration of 10 mg/mL (negligible powder volume). The prescribed dose can then be administered by IV injection slowly over 1-2 minutes.[5-7]

Administration - IM injection (Dunate® and Artesun® brands only):

- Further dilute the reconstituted solution with 2 mL of sodium chloride 0.9 % to achieve a final concentration of 20 mg/mL (Final volume of 3 mL). Administer the prescribed dose via IM injection into the anterior thigh (vastus lateralis preferred site).[7]
- Refer to PCH Guideline Intramuscular Injections (internal link) for further information.

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

- **Compatible fluids:** Sodium chloride 0.9%[7, 9]
- Artesunate is **INCOMPATIBLE** with water for injections.[7]

Compatible at Y-site:

Compatibilities of IV drugs must be checked when two or more drugs are given concurrently.

MONITORING

- Patients should have their lactate dehydrogenase (LDH), haemoglobin and haematocrit monitored during treatment and weekly for 4 weeks after completion for signs and symptoms of post artesunate haemolytic anaemia. Haemolytic anaemia may be more common in those with a higher parasite load on presentation.[4-6, 8]

- Parasite count should be monitored daily until the parasite count is no longer detectable.[3]
- Additional monitoring is required as per the Emergency Department Malaria guideline

ADVERSE EFFECTS

Common: fever, nausea, vomiting, diarrhoea, abdominal pain haemoglobinuria, jaundice, acute renal failure, elevated hepatic enzymes, anaemia, thrombocytopaenia, leucocytosis, neutropenia, leucopenia, lymphopenia, reticulopenia, disseminated intravascular coagulation, acute respiratory distress syndrome, pneumonia, pulmonary oedema, rhinitis, altered taste, bradycardia, cough, dizziness, hypotension, headache.[5, 8]

Infrequent: loss of balance, hemiplegia / paresis, ataxia, neuropsychiatric symptoms, tremor, weakness, confusion, restlessness, hyperbilirubinaemia [5, 8]

Rare: haemolysis (delayed), anaphylaxis or other hypersensitivity reactions, skin reactions including Stevens Johnson Syndrome, fatigue, flushing.[5, 8]

STORAGE

- Artesunate vials should be stored below 25 ˚C and protected from light.[7]
- Once reconstituted, the solution should be used immediately due to poor stability..[7]

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 **artesunate**. 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
- Emergency Department - Malaria

References

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3. Antibiotic Writing Group. Therapeutic Guidelines - Antibiotic. West Melbourne: Therapeutic Guidelines Ltd; 2025. Available from: https://tgldcdp-tg-org-au.pklibresources.health.wa.gov.au/etgAccess.
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7. Symons K. Wong Ee. Australian injectable drugs handbook. Abbotsford: The Society of Hospital Pharmacists of Australia; 2023.
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