MONOGRAPH

Amoxicillin Monograph - Paediatric

Scope (Staff):	Medical, Pharmacy, Nursing
Scope (Area):	All Clinical Areas (Perth Children's Hospital)

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

Moderate spectrum penicillin antibiotic.[1-3]

INDICATIONS AND RESTRICTIONS

- Amoxicillin is active against some Gram negative organisms (e.g. *Streptococcus pneumoniae* and *Haemophilus influenzae*) and some gram positive organisms but is inactivated by beta-lactamase producing strains.[3]

Oral and IV: Unrestricted (green) antibiotic

- This is not a restricted agent. Follow standard ChAMP guidelines where appropriate.

CONTRAINDICATIONS

Hypersensitivity to amoxicillin, any component of the formulation or in patients with a history of high-risk allergy to penicillins.[1, 2, 4-9]

PRECAUTIONS

- Beta-lactam allergy:
  - Amoxicillin 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.
  - In patients with a previous low risk reaction to amoxicillin 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.

- Rapid IV injection of large doses may result in seizures.[2]
- A widespread dull red, maculopapular rash may occur in children receiving amoxicillin.[2] The rash tends to occur after 7 days of commencing therapy and usually resolves 1-7 days after treatment is stopped. It is more common in patients with infectious mononucleosis, acute lymphoblastic leukaemia, chronic lymphocytic leukaemia and HIV infection. The rash should be evaluated to differentiate an immediate hypersensitivity reaction from a delayed hypersensitivity reaction to amoxicillin.[2, 4]
- Sodium accumulation may occur in patients prescribed high IV doses. Ibiamox® brand contains 3.3 mmol of sodium per 1 g of amoxicillin and Fisamox® brand contains 2.6 mmol of sodium per 1 gram of amoxicillin.[1, 2]
- Patients with phenylketonuria should avoid the oral suspension as some brands contain aspartame.[2, 6]

FORMULATIONS

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

- 1 g powder for injection vial
- 250 mg/5 mL powder for oral suspension
- 250 mg capsules
- 500 mg capsules
- Also available in combination products: refer to Amoxicillin/clavulanic acid monograph.

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Neonates: Refer to Neonatal Medication Protocols

Oral - Children (≥4 weeks to 18 years)

- **Usual dose:** 15 – 25 mg/kg/dose (to a maximum of 1 gram) given 8 hourly. [2, 9, 10]
- **Severe infections (e.g. Pneumococcal empyema oral switch):** 30 mg/kg/dose (to a maximum of 1 gram) given 8 hourly.[2, 9, 10]
- **Acute otitis media (low risk of Chronic Suppurative Otitis Media):**
  - **Usual dose:** 15 mg/kg/dose (to a maximum of 1 gram) 8 hourly.[3, 11]
  - Refer to Ear Nose, Throat and Dental Infections Guideline for guidance on treatment of ear infections with a high risk of Chronic suppurative Otitis Media.

IV – Children (≥ 4 weeks to 18 years):

- **Usual dose:** 25 mg/kg/dose (to a maximum of 1 gram) given 8 hourly.[2, 10]
- **Severe infections:** 50 mg/kg/dose (to a maximum of 2 grams) given 4 to 6 hourly.[2, 10]

Note: 4 hourly dosing is usually reserved for treatment of endocarditis or meningitis and should only be used on the advice of Infectious Diseases.[3]

Endocarditis Prophylaxis (high risk):

- **Oral (≥4 weeks to 18 years):** 50 mg/kg (to a maximum of 2 grams) as a single dose given 30 to 60 minutes prior to the procedure.[3, 6, 10]
- **IV (≥4 weeks to 18 years):** 50 mg/kg (to a maximum of 2 grams) as a single dose given within the 60 minutes before the procedure, if oral prophylaxis is not possible.[3, 6, 10]

Pneumococcal prophylaxis in asplenic or hyposplenic patients:

- **Oral (≥4 weeks):** 20 mg/kg/dose (to a maximum of 250 mg) once daily.[3]

Nephrotic syndrome:

- **Oral (≥4 weeks):** 20 mg/kg/dose (to a maximum of 250 mg) once daily. For duration of prophylaxis, refer to: Nephrotic Syndrome Management.

Dosing in Overweight and Obese Children: Dose based on measured body weight.[12]

Renal impairment:

eGFR calculator

- The use of high parenteral doses and/or prolonged treatment in renal impairment may result in electrolyte disturbance and sodium accumulation (due to the high sodium content), neurotoxicity (due to accumulation of the penicillin) and crystalluria.[5]
- Suggested dose adjustments:

eGFR	Recommended dose adjustment[3]
≥ 50 mL/minute/1.73m^2	normal dose
≥ 30 to < 50 mL/minute/1.73m^2	100% – administered up to 6 hourly
≥ 10 to < 30 mL/minute/1.73m^2	100% – administered up to 8 hourly
< 10 mL/minute/1.73m^2	100% – administered 12 hourly

Hepatic impairment:

- No dose adjustment is required in hepatic impairment.[6, 9]

RECONSTITUTION & ADMINISTRATION

IV reconstitution:

- Reconstitute each vial with the volume of water for injection in the table below. Further dilution with a compatible fluid is required prior to administration.[1]

Vial strength	Volume of water for injection required[1, 4]	Resulting concentration
1 gram (Fisamox® or Ibiamox® brand)	9.2 mL (powder volume 0.8 mL)	100 mg/mL

- A transient pink or slight opalescence may appear during reconstitution.[1, 13]

IV administration:

- **Doses < 30 mg/kg/dose:** Dilute reconstituted solution to a concentration of 50 mg/mL or less and inject over 10 to 15 minutes. If required, a slow push over 3 to 4 minutes may be used.[1, 13]

  Avoid rapid administration of large doses, as it may result in seizures.[1, 2]
- **Doses ≥ 30 mg/kg/dose:** Dilute reconstituted solution to a concentration of 50 mg/mL or less and infuse over 30 minutes.[1, 13]

IM injection:

- If IV access is not available, amoxicillin may be given by IM injection into a large muscle. Doses > 500 mg should be split between multiple injection sites.[1, 13] See Intramuscular (IM) Injections.
- **NOTE:** Preparations with lidocaine 1% (10 mg/mL) as diluent must NEVER be given intravenously.[1]

Vial strength	Volume lidocaine 1% (10 mg/mL) *OR* water for injection required[1, 4]	Resulting concentration
1 gram	3.2 mL (powder volume 0.8 mL)	250 mg/mL

Oral suspension (250 mg/5 mL) reconstitution:

- Reconstitute the amoxicillin 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 14 days.[4]

Oral administration:

- Shake well prior to measuring out a dose of the suspension.
- Oral amoxicillin may be administered without regard to the timing of food intake.[2, 4, 6]

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

Compatible fluids:

- Glucose 5%
- Glucose 5% with sodium chloride 0.45%
- Hartmann's
- Sodium Chloride 0.9%[1]

Compatible at Y-site:

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

MONITORING

- Renal, hepatic and haematological function should be monitored weekly with prolonged high-dose therapy (i.e. longer than 7 days).[2, 5, 6]

ADVERSE EFFECTS

Common: widespread erythematous maculopapular rash (generally self-resolving after treatment is ceased), diarrhoea, nausea, pain and inflammation at the injection site, allergy.[2, 5]

Infrequent: vomiting, *Clostridioides difficile*-associated disease[2]

Rare: crystalluria (with high IV doses), black tongue, electrolyte disturbance (hypernatraemia or hypokalaemia due to the high sodium content of the IV formulation), neurotoxicity (usually with high doses, e.g. drowsiness, hallucinations, coma, seizures), bleeding, blood dyscrasias (neutropenia or thrombocytopenia), haemorrhagic colitis, hyperkinesia, vasculitis, dizziness, pustular drug reaction.[2, 5]

Immunologic reactions: include rash (usually maculopapular), erythema, urticaria, contact dermatitis, fever, anaphylactic shock, angioedema, bronchospasm, interstitial nephritis, haemolytic anaemia, eosinophilia, serum sickness-like syndrome, severe cutaneous adverse reactions (SCARs).[2, 5]

STORAGE

IV powder for injection:

- Store vials below 25˚C and protect from light.[1, 4]

Oral powder for suspension:

- Store dry powder for suspension below 25˚C. Once reconstituted, the suspension should be stored in a refrigerator between 2°C and 8˚C.
- Discard any remaining suspension 14 days after reconstitution. Some available brands may be stored at 25˚C for 14 days after reconstitution. Refer to the product information of each brand.[4]

Capsules:

- Store below 25˚C.[4]

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 **amoxicillin**. Any variations to the doses recommended should be clarified with the prescriber prior to administration

Related CAHS internal policies, procedures and guidelines

Children's Antimicrobial Management Program Policy

ChAMP Empiric Guidelines and Monographs

KEMH Neonatal Medication Protocols

References

1. Symons K. Wong Ee. Australian injectable drugs handbook. Abbotsford: The Society of Hospital Pharmacists of Australia; 2023.
2. Australian Medicines Handbook. Adelaide, S. Aust.: Australian Medicines Handbook; 2025 [cited 2025 17th June]. Available from: https://amhonline-amh-net-au.pklibresources.health.wa.gov.au/.
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.
4. AusDI [Internet]. Health Communication Network Pty Ltd. 2025 [cited 2025 June 17th].
5. Paediatric Formulary Committee. BNF for Children: 2025. London: BMJ Group Pharmaceutical Press; 2025.
6. Clinical Pharmacology powered by ClinicalKey [Internet]. Elsvier. 2025 [cited 2025 June 17th]. Available from: https://www-clinicalkey-com.pklibresources.health.wa.gov.au/pharmacology/.
7. Electronic Medicines Compendium (emc). Surrey: DataPharm Ltd; 2024.
8. IBM Micromedex [Internet]. Truven Health Analytics. 2025 [cited 2025 June 17th]. Available from: http://www-micromedexsolutions-com.pklibresources.health.wa.gov.au/micromedex2/librarian.
9. Up To Date - Paediatric Drug information [Internet]. Lexicomp. 2025 [cited 2025 June 17th]. Available from: https://www-uptodate-com.pklibresources.health.wa.gov.au/contents/table-of-contents/drug-information/pediatric-drug-information.
10. 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.
11. Leach AJ, Morris PS, Coates HL, Nelson S, O'Leary SJ, Richmond PC, et al. Otitis media guidelines for Australian Aboriginal and Torres Strait Islander children: summary of recommendations. Med J Aust. 2021;214(5):228-33.
12. Kendrick JG, Carr RR, Ensom MH. Pediatric Obesity: Pharmacokinetics and Implications for Drug Dosing. Clin Ther. 2015;37(9):1897-923.
13. Paediatric Injectable Guidelines 9th Ed [Internet]. Royal Children's Hospital 2024.

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