



## MONOGRAPH

# Amoxicillin Monograph - Paediatric

<b>Scope (Staff):</b>	Medical, Pharmacy, Nursing
<b>Scope (Area):</b>	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

<a href="#">Dosage/Dosage Adjustments</a>	<a href="#">Administration</a>	<a href="#">Compatibility</a>	<a href="#">Monitoring</a>
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### DRUG CLASS

Moderate spectrum penicillin antibiotic.<sup>(1)</sup>

### INDICATIONS AND RESTRICTIONS

- Amoxicillin is active against some Gram negative organisms (e.g. *Escherichia coli* and *Haemophilus influenzae*) and some gram positive organisms but is inactivated by beta-lactamase producing strains.<sup>(2)</sup>
- Common indications include: community acquired pneumonia, acute otitis media, endocarditis prophylaxis, urinary tract infections and pneumococcal prophylaxis in asplenic or hyposplenic patients.<sup>(1, 3, 4)</sup>

#### Oral: 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.<sup>(1, 5)</sup>

### 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 [ $>1$ hr 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.<sup>(1)</sup>
- A widespread dull red, maculopapular rash may occur in children receiving amoxicillin.<sup>(1)</sup> 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.<sup>(1)</sup>
- Sodium accumulation may occur in patients prescribed high IV doses. Amoxil<sup>®</sup> and Ibiamox<sup>®</sup> brands contain 3.3mmol of sodium per 1g of amoxicillin and Fisamox<sup>®</sup> brand contain 2.6mmol of sodium per 1 gram of amoxicillin.<sup>(1, 6)</sup>
- Patients with phenylketonuria should avoid the oral suspension as some brands contain aspartame.<sup>(1)</sup>

## FORMULATIONS

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

- 1g powder for injection vial
- 250mg/5mL powder for oral suspension
- 250mg capsules
- 500mg 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 ( $\geq 4$ weeks to 18 years)

- **Usual dose:** 15-25mg/kg/dose (to a maximum of 1g) 8 hourly.<sup>(1, 2, 4)</sup>
- **Severe infections (e.g. Pneumococcal empyema oral switch):** 30mg/kg/dose (to a maximum of 1g) 8 hourly.<sup>(4)</sup>

- **Acute otitis media (low risk of Chronic Suppurative Otitis Media):**
  - **Usual dose:** 15mg/kg/dose (to a maximum of 1gram) 8 hourly.<sup>(1, 7)</sup>
- **Ear infections (high risk of Chronic Suppurative Otitis Media/ Aboriginal or Torres Strait Islander):**
  - **Acute otitis media – without perforation:** 15mg/kg/dose (to a maximum of 1gram) 8 hourly for 7 days. IF no response after 4 to 7 days, the dose may be increased to 30mg/kg/dose (to a maximum of 1gram) 8 hourly for a further 7 days.<sup>(1, 7)</sup>
  - **Acute otitis media – with perforation:** 30mg/kg/dose (to a maximum of 1gram) 8 hourly for 14 days.<sup>(1, 7)</sup>
  - **Persistent otitis media with effusion OR recurrent otitis media:** 25mg/kg/dose (to a maximum of 1gram) 12 hourly for 3 to 6 months.<sup>(1, 7)</sup>

Please see [Ear Nose, Throat and Dental Infections Guideline for further information.](#)

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

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

**Note:** 4 hourly dosing is usually reserved for treatment of endocarditis or meningitis and should only be used on the advice of Infectious Diseases.<sup>(2)</sup>

#### **Endocarditis Prophylaxis (high risk):**

- **Oral (≥4 weeks to 18 years):** 50mg/kg (to a maximum of 2grams) as a single dose given 1 hour prior to the procedure.<sup>(1, 2)</sup>
- **IV (≥4 weeks to 18 years):** 50mg/kg (to a maximum of 2grams) as a single dose given within the 60 minutes before the procedure, if oral prophylaxis is not possible.<sup>(1, 2, 4)</sup>

#### **Pneumococcal prophylaxis in asplenic or hyposplenic patients:**

- All ages: 20mg/kg/dose (to a maximum of 250mg) once daily.<sup>(2)</sup>

#### **Dosing in Overweight and Obese Children:**

- Dose based on measured body weight.

#### **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.<sup>(1, 3)</sup>
- The risk of neutropenia and rash may also be increased.<sup>(1, 3)</sup>
- Suggested dose adjustments:
  - eGFR ≥ 50mL/minute: normal dose
  - eGFR ≥30 to <50mL/minute: 100% dose 6 hourly
  - 
  - eGFR ≥10 to <30mL/minute: 100% dose 8 hourly.
  - eGFR <10mL/minute: 100% dose 12 hourly.<sup>(2)</sup>

**Hepatic impairment:**

- No dose adjustment is required in hepatic impairment.<sup>(5)</sup>

**RECONSTITUTION & ADMINISTRATION****IV reconstitution:**

- Reconstitute each vial with the volume of water for injection in the table below. Further dilution with a compatible fluid to a concentration of 50mg/mL or weaker is required prior to administration.<sup>(6)</sup>

Vial strength	Volume of water for injection required <sup>(6, 8, 9)</sup>	Resulting concentration
1 gram (Fisamox® or Ibiamox® brand)	9.3mL (powder volume 0.7mL)	100mg/mL
1 gram (Amoxil® brand)	9.2mL (powder volume 0.8mL)	100mg/mL

- A transient pink or slight opalescence may appear during reconstitution.<sup>(6, 9)</sup>

**IV administration:**

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

Avoid rapid administration of large doses, as it may result in seizures.<sup>(1, 6, 9)</sup>

- Doses ≥30mg/kg/dose:** Dilute reconstituted solution to a concentration of 50mg/mL or weaker and infuse over 30 minutes.<sup>(1, 6, 9)</sup>

**IM injection:**

- If IV access is not available amoxicillin may be given by IM injection into a large muscle. Doses >500mg should be split between multiple injection sites.<sup>(6)</sup>
- NOTE:** Preparations with lidocaine (lignocaine)1% (10mg/mL) as diluent must NEVER be given intravenously.<sup>(6)</sup>

Vial strength	Volume lidocaine (lignocaine) 1% (10mg/mL) OR water for injection required <sup>(6)</sup>	Resulting concentration
1 gram	3.3mL (powder volume 0.7mL)	250mg/mL

**Oral suspension (250mg/5mL) 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.<sup>(9)</sup>

**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.<sup>(1, 5, 9)</sup>

**COMPATIBILITY (LIST IS NOT EXHAUSTIVE)**

**Compatible fluids:**

- Glucose 5%
- Glucose 5% with sodium chloride 0.45%
- Hartmann's
- Sodium Chloride 0.9%<sup>(6)</sup>

**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).<sup>(1)</sup>

**ADVERSE EFFECTS**

**Common:** widespread erythematous maculopapular rash (generally self-resolving after treatment is ceased), diarrhoea, nausea, pain and inflammation at the injection site, superinfection (including candidiasis), allergy.<sup>(1)</sup>

**Infrequent:** vomiting, *Clostridioides difficile*-associated disease<sup>(1)</sup>

**Rare:** crystalluria (with high IV doses), black tongue, electrolyte disturbance (hypernatraemia or hypokalaemia), neurotoxicity (usually with high doses, e.g. drowsiness, hallucinations, coma, seizures), bleeding, blood dyscrasias (neutropenia or thrombocytopenia), haemorrhagic colitis, hyperkinesia, vasculitis, dizziness.<sup>(1, 3, 5)</sup>

**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).<sup>(1, 3)</sup>

**STORAGE**

**IV powder for injection:**

- Store vials below 25°C and protect from light. Use immediately after reconstitution and discard any excess solution.<sup>(6, 9)</sup>

**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.<sup>(9)</sup> Some available brands may be stored at 25°C for 14 days after reconstitution. Refer to packaging of each brand.<sup>(9)</sup>

**Capsules:**

- Store below 25°C<sup>(9)</sup>

## 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

[Antimicrobial Stewardship Policy](#)

[ChAMP Empiric Guidelines and Monographs](#)

[KEMH Neonatal Medication Protocols](#)

## References

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## Healthy kids, healthy communities

Compassion

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