MONOGRAPH	
Amoxicillin (Amoxycillin) Monograph - Paediatrics	
Scope (Staff):	Medical, Nursing, Pharmacy
Scope (Area):	Perth Children's Hospital (PCH)

This document should be read in conjunction with this DISCLAIMER

DESCRIPTION	• Amoxicillin is a bactericidal penicillin antibiotic which interferes with cell wall peptidoglycan synthesis by binding to penicillin-binding proteins resulting in cell lysis.[1-3] • Amoxicillin is a moderate spectrum penicillin active against some Gram negative organisms (e.g. *Eshcerichia coli* and *Haemophilus influenzae*) and some gram positive organisms but is inactivated by beta-lactamase producing strains.[4]
INDICATIONS AND RESTRICTIONS	• **Oral and IV: Unrestricted (green) antibiotic** • This is not a restricted agent. Follow standard ChAMP guidelines where appropriate.
CONTRAINDICATIONS	• Amoxicillin is generally contraindicated in patients with a history of high risk allergy to penicillins.[1]
PRECAUTIONS	• 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 may result in seizures.[1] • A generalised dull red, maculopapular rash may occur in 5 to 10% of children receiving amoxicillin. • 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.[3]

FORMULATIONS	**Available at PCH:** • 1g powder for injection vial • 250mg/5mL powder for oral suspension • 250mg capsules • 500mg capsules **Other formulations:** • 1g powder for injection vial (multiple generic brands available) • 250mg/5mL, 125mg/5mL and 100mg/mL powder for oral suspension (multiple generic brands available) • 250mg and 500mg capsules (multiple generic brands available) • 1000mg tablets
DOSAGE	• The doses listed below fall within the standard range. Higher doses may be prescribed for certain situations. • This should be in consultation with an infectious diseases or clinical microbiology consultant. **Neonates (less than 30 days of age):** • Please refer to neonatal clinical care drug protocols **Oral (>1month to 18 years):** • **Usual dose:** 15-25mg/kg/dose (to a maximum of 500mg) 8 hourly.(1) • For patients with otitis media, please refer to the Ear Nose and Throat Guideline • **Severe infections or suspected partial non-susceptibility:** 30mg/kg/dose (to a maximum of 1gram) 8 hourly.(1) **IV (>1month to 18 years):** • Usual dose: 25mg/kg/dose (to a maximum of 1gram) 8 hourly. • Severe infections: 50mg/kg/dose (to a maximum of 2grams) 4 to 6 hourly.(1, 4) • **Note:** 4 hourly dosing is usually reserved for treatment of endocarditis or meningitis.(2) **Endocarditis Prophylaxis:** • **Oral (>1month to 18 years):** 50mg/kg (to a maximum of 2grams) as a single dose given 1 hour prior to the procedure.(1, 4) • **IV (>1month to 18 years):** 50mg/kg (to a maximum of 2grams) as a single dose given 15 to 60 minutes prior to the procedure, if oral prophylaxis is not possible.(1, 4)

Pneumococcal prophylaxis in asplenic or hyposplenic patients:

- All ages: 20mg/kg/dose (to a maximum of 250mg) once daily.[4]

DOSAGE ADJUSTMENT

Dosage adjustment required in renal impairment:

- To calculate the estimated glomerular filtration rate (eGFR) use the following formula:

$$eGFR\ (mL/min/1.73m^2) = \frac{36.5 \times height\ (in\ cm)}{Serum\ creatinine\ (micromol/L)}$$

- The use of high parenteral doses and/or prolonged treatment in renal impairment may result in electrolyte disturbance (due to the high sodium content), neurotoxicity (due to accumulation of the penicillin) and crystalluria.
- The risk of neutropenia and rash may also be increased.[2]
- CrCl ≥ 50mL/minute = normal dose
- CrCl 10- 50mL/minute = 100% of dose 8 to 12 hourly.
- CrCl <10mL/minute = 100% of dose 12 hourly.[4]

Dosage adjustment required in hepatic impairment:

No dose adjustment is required in hepatic impairment.[3, 5]

RECONSTITUTION

IV:

- 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 is required prior to administration.[6, 7,8]

Vial strength	Volume of water for injection required	Resulting concentration
1 gram	9.3mL	100mg/mL

- A transient pink or slight opalescence may appear during reconstitution.[6]
- Oral suspension (250mg/5mL):
- 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.
ADMINISTRATION	**IV injection:** • For doses < 30mg/kg, dilute reconstituted solution to a concentration of 50mg/mL or less and inject over 3 to 4 minutes. Avoid rapid administration of large doses, as it may result in seizures.[1, 7, 8] **IV infusion:** • For doses ≥30mg/kg, dilute reconstituted solution to a concentration of 50mg/mL or weaker and infuse over 30 minutes.[7, 8] **IM injection:** • If IV access is not available this medication may be given by IM injection into a large muscle. Doses >500mg should be split between multiple injection sites.[7,8] **Oral:** • Shake well prior to measuring out a dose of the suspension. Oral amoxicillin may be administered without regard to the timing of food intake.[3, 6]
MONITORING	• Renal, hepatic and haematological function should be monitored weekly with prolonged therapy (i.e. longer than 7 days).[1, 3, 6]
ADVERSE EFFECTS	**Common:** widespread erythematous maculopapular rash (generally self-resolving after treatment is ceased), diarrhoea, nausea, pain and inflammation at the injection site, candidiasis, allergy, hypersensitivity reaction, joint pain.[1, 2] **Rare:** pustular drug eruption, crystalluria (with high IV doses), vomiting, *Clostridium difficile*-associated disease, black tongue, electrolyte disturbance (hypernatraemia or hypokalaemia), CNS irritation, neurotoxicity or encephalopathy (usually with high doses), bleeding, blood dyscrasias (neutropenia or thrombocytopenia)[1, 2] **Immunologic reactions:** include rash, erythema, urticaria, contact dermatitis, fever, anaphylactic shock, angioedema, bronchospasm, interstitial nephritis, haemolytic anaemia, eosinophilia, serum sickness-like syndrome, exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis.[1]
COMPATIBLE FLUIDS	• Glucose 5% • Glucose 5% with sodium chloride 0.45% • Sodium Chloride 0.9%[7,8]
STORAGE	**IV powder for injection:** • Store vials below 25˚C, use immediately after reconstitution and discard any excess solution.

	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. **Capsules:** • Store below 25˚C[6]
INTERACTIONS	**Amoxicillin may interact with other medications; please consult PCH approved references (e.g. Clinical Pharmacology), your ward pharmacist or Pharmacy on extension 63546 for more information.** • IV aminoglycoside antibiotics (e.g. gentamicin and tobramycin) are inactivated by IV penicillins and cephalosporins. Aminoglycoside antibiotics are rapidly bactericidal and should be administered first. The line should then be flushed well with a compatible fluid and the penicillin administered.[7] • Amoxicillin inhibits methotrexate excretion and may result in excessive methotrexate levels.[6] • The use of allopurinol and amoxicillin together significantly increases the incidence of rash.[1, 6] • Amoxicillin increases the absorption of digoxin, increasing levels. A reduction in the dose of digoxin may be required.[1, 6] • The use of amoxicillin with warfarin or other coumarin derivatives may result in an increase in the INR and/or prolonged bleeding time. Monitor closely.[1, 2]
COMMENTS	
MANUFACTURER SAFETY DATA SHEET (SDS)	To access to the Manufacturer SDS for this product, use the following link to ChemAlert.

Please note: The information contained in this guideline is to assist with the preparation and administration of **amoxicillin (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 and related external legislation, policies, and guidelines

1. Rossi S, editor. Australian Medicines Handboook 2019. Adelaide, S. Aust.: Australian Medicines Handbook; 2019.
2. Paediatric Formulary Committee. BNF for Children: 2019. London: BMJ Group Pharmaceutical Press; 2019.
3. Taketomo CK, Hodding JH, Kraus DM, Hodding JH. Pediatric and Neonatal dosage handbook with international trade names index. 241th ed. Ohio: Lexi-comp; 2017-2018.
4. Antibiotic Writing Group. Therapeutic Guidelines - Antibiotic. West Melbourne: Therapeutic Guidelines Ltd; 2019. Available from: http://online.tg.org.au.pklibresources.health.wa.gov.au/ip/.
5. Clinical Pharmacology [Internet]. Elsvier BV. 2019 [cited 03/07/2019]. Available from: http://pklibresources.health.wa.gov.au/login?url=http://www.clinicalpharmacology-ip.com/?id=24317714.
6. MIMS Australia. MIMS online [full product information]. St Leonards, N.S.W: CMP Medica Australia.; 2019. p. 1v. (various pagings).
7. Burridge N Deidun D Collard N (editors). Australian injectable drugs handbook. Collingwood: The Society of Hospital Pharmacists of Australia; 2019.
8. Royal Children's Hospital Melbourne. Paediatric Injectable Guidelines. Melbourne: Pharmacy department: Royal Children's Hospital; 2019.

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