Waikato District Health Board	Type: **Drug Guideline**	Document reference: **0582**	Manual Classification: **Waikato DHB Drug Guidelines**
Title: **Amoxicillin/clavulanic acid for Neonates**			Effective date: **20 August 2020**
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BRIEF ADMINISTRATION GUIDE

For detailed information refer to The Australasian Neonatal Medicines Formulary **amoxicillin-clavulanate** guideline

Critical Note: there are minor variations between the ANMF and Waikato DHB best practice within this drug guideline – see yellow shaded text

Indications:
- Bacterial infections otherwise resistant to amoxicillin
- Suspected infections of gastrointestinal origin e.g. NEC

Route: Intravenous, or oral
- Injection supplied as amoxicillin 500 mg plus clavulanic acid 100 mg
- Oral supplied as amoxicillin 250 mg/5mL plus clavulanic acid 62.5 mg/5mL (i.e. amoxicillin/clavulanic acid 312.5 mg/ 5 ml) suspension

Dose: NOTE: doses are expressed as the **combination** of amoxicillin and clavulanic acid
e.g. a 30 mg IV dose contains 25 mg amoxicillin and 5 mg clavulanic acid

Route	**Dose** (mg/kg/dose)	**Postnatal age** (days)	**Dosing Interval** (hours)
IV	30	0 to 7	12
		>7	8

Oral dosing for non-systemic infections: 15-30mg/kg three times daily

Preparation and administration:

Intravenous
- Dilute 600mg vial with 9.7 mL of water for injection to make concentration 60 mg/mL.
  Shake vial vigorously, as soon as diluent is added, to dissolve powder and check for absence of particulate matter before proceeding.
  Babies >1kg (dose >30mg): Dilute further by taking 3.3 mL of this solution and make up to 10mL with sodium chloride 0.9% to give a final concentration of 20 mg/mL (maximum recommended concentration).
  Babies ≤1kg: Dilute further by taking 1.7 mL of the original solution from the vial and make up to 10 mL with sodium chloride 0.9% to give a final concentration of 10 mg/mL.
- Draw up the required volume for the dose
- Infuse dose **over 30 minutes** using Guardrails profiled syringe driver
- Flush before and after the dose with sodium chloride 0.9% (preferably) or glucose 5 or 10 %.
  Note: although amoxicillin/clavulanic acid is reported to be unstable with glucose (the medication degrades faster) it is deemed acceptable to flush with or administer concurrently when necessary.
  The flush should be administered at the same rate as the amoxicillin/clavulanic acid.

Oral
- Final concentration using the 250/62.5 mg strength amoxicillin/clavulanic acid product is 62.5 mg/mL.
- If ordering from Pharmacy the suspension will already be reconstituted, but if not follow the directions below:
  - Shake the bottle to loosen the powder.
  - Check instructions on bottle for volume of water to make up to 100 mL e.g. Augmentin® and Curam® brand: add 90 ml of water if using 250/62.5 mg strength. Shake well.
  - When first reconstituted allow to stand for 5 minutes to ensure full dispersion.
- Shake suspension well then draw up appropriate volume for the dose in an oral syringe. Can be diluted further with sterile water or milk if required. After mixing administer immediately.
  If possible administer at the beginning of a feed to help minimise gastric side effects.

Monitoring

- Consider if specimen for culture and sensitivity testing is required before first dose
- Assess for signs of anaphylaxis and adverse reactions
- Observe infusion site for thrombophlebitis
- Monitor temperature and other parameters appropriate to the condition
- Observe for change in bowel frequency
- Monitor renal, hepatic and hematologic function periodically

Storage and Stability

- Discard any remaining solution in the vial. Administer the dose within 60 minutes of preparation.
- Diluted IV solutions (in sodium chloride 0.9%) are stable for up to 4 hours when refrigerated
- The reconstituted suspension is stable for 7 days when refrigerated

Competency for Administration

This procedure is carried out by, or under, the direct supervision of a registered nurse/registered midwife who holds current Waikato DHB Generic Medicine Management and IV certification plus Guardrails competency (if administering IV) as well as Neonatal specific competency NCV/NAC (if administering via CVAD).

Guardrails Information

Amoxicillin/clavulanic acid is Guardrail profiled on the CC pump for NICU. Following are the guardrail limits:

Guardrails Drug Name	**Amoxicillin/clav***	
Pump	**CC**	
	0.4-1kg	**1-5kg**
Concentration (mg/ml)		
Minimum	7.5	10
Maximum	20	20
Dose rate (mg/kg/hour)		
Default	60	60
Soft minimum	40	40
Soft maximum	60	60
Hard max	62	62

References

- Australian Neonatal Medicines Formulary. Amoxicillin-clavulanate Drug Guideline, 2020. Available from: https://www.slhd.nsw.gov.au/RPA/neonatal%5Ccontent/pdf/Medications_Neomed/Amoxicillin-clavulanate_ANMFv1.2_full_20200716.pdf
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