Waikato District Health Board	Type: **Drug guideline**	Document reference: **0562**	Manual Classification: **Waikato DHB Drug guidelines**
Title: **Amikacin for Neonates**			Effective date: **20 August 2020**
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BRIEF ADMINISTRATION GUIDE

For detailed information refer to The Australasian Neonatal Medicines Formulary **amikacin** guideline

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

Indications:
- Suspected or proven neonatal sepsis resistant to other aminoglycosides
- Late sepsis (≥2 days) empiric therapy (in combination with flucloxacillin)

Route:

Intravenous, preferably via peripheral line (avoid umbilical lines)
- Supplied as:
  - amikacin prefilled syringes 5 mg/mL (50 mg/10 mL or 25 mg/5 mL)
  - amikacin 500 mg / 2 mL vial
- pH approx. 3.5 to 5.5

Dose:

Corrected Gestation Age (weeks)	Postnatal Age (days)	Dose (mg/kg)	Interval (hours)
≤ 29	0-7	14	48
	8-28	12	36
	≥29	12	24
30 – 34	0-7	12	36
	≥8	12	24
≥ 35	All	12	24
• Perinatal asphyxia on therapeutic hypothermia • Indomethacin / ibuprofen treatment			Increase above intervals by 12h

Dosage should be based on actual weight/birthweight (unless the patient has hydrops fetalis when an adjusted weight should be used)

Charting
- Chart dose and frequency on the medication chart i.e. normal prescribing
- Indicate (in administration section of the medication chart) the date and time of next trough level to be taken, to check dosing interval is appropriate (see "serum levels" below e.g. before second dose for 36 and 48 hour dosing, and before the third dose for 24 hour dosing)

Serum levels:
- Routine therapeutic drug monitoring for <36 hours duration of therapy is not necessary unless renal function is impaired
- **Obtain trough levels 1h prior to next dose** if drug being continued (following 36 hour period) and withhold the dose while result is awaited i.e. if interval is 36 or 48 hours then obtain level before 2nd dose, if 24 hour interval level before 3rd dose.
- Aim for **trough of ≤5** microgram/mL and adjust dosing interval accordingly (extend interval by the time it takes for the level to get ≤ 5):

Trough Level (mcg/mL)	Suggested action
≤ 5	no change
5.1 to 8	repeat trough level 12h later
8.1 to 10.5	repeat trough level 24h later
≥ 10.6	repeat trough level 48h later

- Repeat trough levels prior to the next dose if amikacin interval is changed. If stable; check level prior to every third dose, unless changing fluid or renal status (then check more frequently)

Note: Peak levels are only indicated if the organism has a high minimum inhibitory concentration – speak with a Microbiologist if using for non-standard indications.

Preparation and administration

Intravenous Infusion

- Select the appropriate sized prefilled syringe depending on the dose required.
  If prefilled syringes are not available prepare the solution as follows:
  - Draw up 1 mL (= 250 mg) from vial and dilute with 4 mL of compatible fluid (sodium chloride 0.9%, dextrose 5%, dextrose 10%, sodium chloride /glucose combination) making a solution of 50 mg/mL
  - Take 1 mL of this resulting 50 mg/mL solution and dilute to 10 mL with compatible fluid, to make 10 mL of a **5 mg/mL** solution.

  Note: maximum concentration of 50 mg/mL if fluid restricted and has a CVAD.
- Draw up required dose and administer by intravenous infusion **over 1 hour**, using Guardrails.
- Follow injection with a flush administered at the same rate as the amikacin to ensure the full dose is delivered.
- Note: aminoglycoside antibiotics are inactivated by IV cephalosporins and penicillins. Preferably separate doses by 1 hour. If it is not possible to separate doses by 1 hour, administer amikacin first and flush the line well with a compatible fluid before and after giving each medicine

Monitoring

- Observe for adverse effects and injection site reactions.
- Monitor urinalysis, urine output, electrolytes, serum creatinine, serum amikacin concentrations
- Correct dehydration before initiation therapy and maintain adequate hydration throughout
- Audiology testing is recommended for longer term treatment where possible (CPAP and ventilation are too noisy to evaluate hearing), and on discharge from NICU

Storage and Stability

- Discard any remaining solution in the prefilled syringe
- Any unused vial contents can be stored at room temperature and used within 24 hours

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. For CVAD administration Neonatal specific competency NCV/NAC is also required.

Guardrails

Amikacin is Guardrail profiled on the CC pump for NICU. Following are the guardrail limits:

Guardrails Drug Name	**Amikacin***			
Pump	CC			
	0.4-1kg	**1-2kg**	**2-3kg**	**3-5kg**
Concentration (mg/ml)				
Minimum	3	4.9	4.9	4.9
Maximum	15	30	50	50
Default	5	5	5	5
Administration Rate (mg/kg/hr)				
Soft minimum	6	6	6	6
Default	12	12	12	12
Soft maximum	40	40	40	40
Hard maximum	50	50	50	50

References:

- Royal Prince Alfred Hospital NeoMed Consensus Group. Amikacin Drug Information Sheet. June 2019. Available from: https://www.slhd.nsw.gov.au/rpa/neonatal/NeoMedPaperCopy.html
- New Zealand Formulary for Children (NZFC). 2020. Amikacin. Accessed 3rd February 2020. Available from: https://www.nzfchildren.org.nz/nzf_3137
- Truven Health Analytics Inc. Pediatrics and Neofax®. 2018. Amikacin monograph. Accessed 31st August 2018. Available from: http://www.micromedexsolutions.com.
- Phelps SJ, Hagemann TM, Lee KR, Thompson AJ. The Teddy Bear Book: Pediatric Injectable Drugs. 10th edition. American Society of Health-System Pharmacists; 2013.
- Pfizer NZ Ltd.. DBL Amikacin Data Sheet. 1 February 2019. Available from: https://www.medsafe.govt.nz/profs/datasheet/a/Amikacininj.pdf
- The Royal Children's Hospital Melbourne. Paediatric Injectable Guidelines. Accessed 3rd February 2020. Available from: https://pig.rch.org.au.
- Notes on Injectable Drugs, 7th Edition, Amikacin. New Zealand Hospital Pharmacists Association. Published 2015, Wellington NZ.
- Waikato DHB Guardrails Database 2018.

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