GENTAMICIN

Indication	• Empiric treatment of suspected early onset sepsis (in combination) • Directed treatment of infections due to susceptible gram-negative organisms (in combination) (e.g. Pseudomonas, Klebsiella, E.coli, Enterobacter cloacae) • Directed treatment in synergistic combination with a beta-lactam antibiotic in severe gram-positive infection (e.g. GBS, enterococcal endocarditis)

INTRAVENOUS

Presentation

- Ampoule: 10 mg in 1 mL | 80 mg in 2 mL

Dosage

- 5 mg/kg (frequency according to corrected age)[1,2]

Current gest age (weeks)	Dosage
29+6 or less	5 mg/kg every 48 hours
30+0–34+6	5 mg/kg every 36 hours
35+0 or more	5 mg/kg every 24 hours

Preparation

- 10 mg/mL ampoule
  - Not required
  - *Concentration equal to 10 mg/mL*
- 80 mg in 2 mL ampoule
  - Draw up 2 mL and make up to 8 mL total volume with 0.9% sodium chloride[3]
  - *Concentration now equal to 10 mg/mL*

Administration

- May be administered by IV injection[4-6] or by IV infusion[3,7] as per local policy
- IV injection
  - Draw up prescribed dose
  - IV injection over 5 minutes
- IV infusion
  - Prime the infusion line and reduce total syringe volume to the prescribed dose
  - IV infusion via syringe driver pump over 20–30 minutes
  - On completion, disconnect syringe and infusion line
  - Flush access port at same rate as infusion

IM

Presentation

- Ampoule: 10 mg in 1 mL | 80 mg in 2 mL

Dosage

- 5 mg/kg (frequency according to corrected age)[1,2]

Current gest age (weeks)	Dosage
29+6 or less	5 mg/kg every 48 hours
30+0–34+6	5 mg/kg every 36 hours
35+0 or more	5 mg/kg every 24 hours

Preparation

- Not required

Administration

- Draw up prescribed dose
- Intramuscular injection into thickest part of the vastus lateralis in the anterolateral thigh (maximum 0.5 mL per site)[8]

Special considerations

- High risk medication. Incorrect dosing may result in significant ototoxicity and nephrotoxicity. Under dosing may result in treatment failure
- May need dose adjustment (monitor drug targets closely) if:
  - Renal impairment[1] (PDA, ibuprofen or other nephrotoxic drug use)
  - Hypothermia for HIE (increased dosing intervals)[1]
- If co-prescribed with cephalosporins, penicillins or teicoplanin give the antibiotic with shortest duration of administration first (so antibiotic cover commences asap)[3]
  - Do not mix in the same injection or infusion solution; flush before and after
- Use IM route only if IV route not available; absorption rate variable[1]
  - For IM injection, 80 mg in 2 mL ampoule (if available) is preferred and results in smaller volume administration
- UAC route: consult with neonatologist/paediatrician prior to use and refer to Queensland Clinical Guideline: *Neonatal medicines*[9]
- Current gestational age is the same as *postmenstrual age* (PMA)

Therapeutic drug monitoring

- Therapeutic drug monitoring only required if:
  - Treating for more than 48 hours (directed therapy following blood culture results)[10]
  - Altered pharmacokinetics (e.g. impaired renal function)[10]
- Peak concentration (therapeutic range 5–12 mg/L)
  - Not commonly monitored in neonates
  - If required, collect 1 hour after dose administration
- Trough concentration (therapeutic range 1–2 mg/L)
  - Collect 30 minutes before third dose. Do not administer third dose until result available
  - Subsequent dosage at consultant discretion according to clinical circumstances
  - A dose interval adjustment based on trough level result is *suggested* below
  - Subsequent monitoring at consultant discretion (not usually required unless impaired renal function)

Trough level (mg/L)	Suggested action
2.0 or less	• Administer third dose • No change to subsequent dose interval
2.1 or more	• Do not administer third dose • Repeat trough in 12 hours • Adjust subsequent interval based on repeat trough

Monitoring

- Renal function (output, serum urea/creatinine)

Compatibility

- Fluids
  - 5% glucose[3], 10% glucose[3], 0.9% sodium chloride[3]
- Y-site
  - Amiodarone[3], atracurium[3], aztreonam[3], caspofungin[3], ciprofloxacin[3], cisatracurium[3], dexmedetomidine[3], esmolol[3], fluconazole[3], foscarnet[3], granisetron[3], hydromorphone[3], linezolid[3], magnesium sulfate[3], midazolam[3], morphine sulfate[3], posaconazole[3], potassium chloride[3], vecuronium[3], zidovudine[3]

Incompatibility

- PN and fat emulsion: co-infusion with gentamicin not recommended (evidence limited). If unavoidable, seek pharmacist advice first, filter infusion and flush before and after
- Fluids
  - 10% fat emulsion[3]
- Drugs
  - Azathioprine[3], azithromycin[3], dexamethasone[3], flucloxacillin[3], folic acid[3], furosemide (frusemide)[3], heparin sodium[3], indometacin[3], propofol[3], teicoplanin[3]

Interactions

- Aminoglycoside inactivated by cephalosporins, penicillins and teicoplanin antibiotics

Stability

- Ampoule[3]
  - Store below 25 °C. Protect from light

Side effects	• Hypersensitivity reactions: rare in neonates. May present as erythema and rash (maculopapular rash, red purple plaques or urticarial type plaques[11-14] • Nervous: ototoxicity caused by damage to hair cells in the ear. Impaired renal function is the most important predisposing factor (i.e. renal immaturity)[1] • Urinary/excretory: nephrotoxicity related to prior renal impairment, high dosage and concurrent use of other potentially nephrotoxic drugs[7] • Muscular: blockage and muscle paralysis[15]
Actions	• Aminoglycoside antibiotic. Inhibits protein synthesis in the bacterial cell[15]
Abbreviations	HIE: hypoxic-ischaemic encephalopathy, IM: intramuscular; IV: intravenous; PDA: patent ductus arteriosus
Keywords	gentamicin, gentamycin, antibiotic, aminoglycoside, early onset sepsis, empiric treatment of sepsis,

The Queensland Clinical Guideline *Neonatal Medicines* is integral to and should be read in conjunction with this monograph. Refer to the disclaimer. Destroy all printed copies of this monograph after use.

References

1. IBM Micromedex® Neofax®. Gentamicin. In: IBM Micromedex® NeoFax®/Pediatrics (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. April 2019 [cited 2019 May 16]. Available from: https://www.micromedexsolutions.com.
2. Bijleveld YA, van den Heuvel ME, Hodiamont CJ, Mathot RA, de Haan TR. Population pharmacokinetics and dosing considerations for gentamicin in newborns with suspected or proven sepsis caused by gram-negative bacteria. Antimicrob Agents Chemother 2017;61(1).
3. Australian Injectable Drugs Handbook. Nicolette Burridge, Keli Symons, editors. Gentamicin. 7th ed. [Internet]. New South Wales: Society of Hospital Pharmacists of Australia (SHPA); June 2021 [cited 2021 August 05]. Available from: https://aidh.hcn.com.au.
4. Bastone EB, Li SC, Ioannides-Demos LL, Spicer WJ, McLean AJ. Kill kinetics and regrowth patterns of Escherichia coli exposed to gentamicin concentration-time profiles simulating in vivo bolus and infusion dosing. Antimicrob Agents Chemother 1993;37(4):914-7.
5. Spencer S, Ipema H, Hartke P, Krueger C, Rodriguez R, Gross AE, et al. Intravenous Push Administration of Antibiotics: Literature and Considerations. Hosp Pharm 2018;53(3):157-69.
6. Bromiker R, Adelman C, Arad I, Shapiro M, Levi H. Safety of gentamicin administered by intravenous bolus in the nursery. Clin Pediatr (Phila) 1999;38(7):433-5.
7. British National Formulary for Children (BNFC) online. Gentamicin. [Internet]: Royal Pharmaceutical Society; December 2017 [cited 2019 May 22]. Available from: https://www.medicinescomplete.com.
8. Hockenberry M, Wilson D. Wong's Nursing Care of Infants and Children. 10th ed. USA: Elsevier; 2014.
9. Queensland Clinical Guidelines. Neonatal medicines. Guideline No. MN19.54-V1-R24. [Internet]. Queensland Health. 2019. [cited 2021 January 15]. Available from: https://www.health.qld.gov.au/qcg
10. Australian Medicines Handbook Children's Dosing Companion. Gentamicin. [Internet]. Adelaide: Australian Medicines Hanbook Pty Ltd; January 2019 [cited 2019 May 22]. Available from: https://amhonline.amh.net.au.
11. Carder KR. Hypersensitivity reactions in neonates and infants. Dermatol Ther 2005;18(2):160-75.
12. Lohmeier K, Megahed M, Schulte KW, Stannigel H, Mayatepek E, Schroten H. Toxic epidermal necrolysis in a premature infant of 27 weeks' gestational age. Br J Dermatol 2005;152(1):150-1.
13. Martini S, Alessandroni R, Arcuri S, Faldella G. Vancomycin-induced red man syndrome presentation in a preterm infant. Pediatr Dermatol 2018;35(6):e408-e9.
14. Maulidi H, Godambe S, Chow P. Suspected drug reaction with piperacillin/tazobactam, in a premature infant. Br J Clin Pharmacol 2008;65(6):971-2.
15. MIMS Online. Gentamicin. [Internet]: MIMS Australia; October 2011 [cited 2018 September 04]. Available from: https://www.mimsonline.com.au.

Document history

ID number	Effective	Review	Summary of updates
NMedQ20.038-V1-R25	01/03/2020	01/03/2025	Endorsed by Queensland Neonatal Services Advisory Group (QNSAG)
NMedQ20.038-V2-R25	01/03/2021	01/03/2025	• Added to special considerations: re volume for administration via IM route • Removed UAC icon and amended instructions for administration via UAC • Amended corrected gest age to current gest age and added statement current gest age is equivalent to PMA • Added QR code
NMedQ20.038-V2-R25	13/08/2021	01/03/2025	• Amended instructions for co-prescription with cephalosporins, penicillins teicoplanin antibiotics to clarify order of administration

QRSCAN